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I. INTRODUCTION

Defendants Halifax Hospital Medical Center (“Halifax”) and Halifax Staffing hereby move for summary judgment. This case, fundamentally, is about two sets of compensation agreements with certain employed physicians (collectively, the “Physicians”).¹ There is no genuine dispute of fact that these agreements do not violate 42 U.S.C. § 1395nn (the “Stark Law”) or result in claims that violate 31 U.S.C. §§ 3729 *et seq.* (the “False Claims Act” or “FCA”). Nor is the United States entitled to the draconian fines and penalties it demands for its hyper-technical reading of the Stark Law.

The Stark Law is a payment rule, administered by the Centers for Medicare and Medicaid Services (“CMS”), that prohibits Medicare payment for certain types of designated health services (“DHS”) if the physician who referred the service has a financial relationship with the entity that provided the service, unless that relationship satisfies one of the exceptions set out in the statute and accompanying regulations. Despite the fact that CMS has vaguely interpreted the Stark Law, Halifax designed its physician agreements in good faith and took the necessary steps to comply with the Stark Law, specifically the criteria of the *Bona Fide* Employment Exception. 42 U.S.C. § 1395nn(e)(2) (hereinafter the “*Bona Fide* Employment Exception”). Pursuant to applicable regulations, Halifax also used reasonable methodologies to assess the fair market value (“FMV”) and commercial reasonableness of the Physicians’ agreements.

Halifax is entitled to summary judgment with respect to all the Neurosurgeon claims because the United States failed to provide any analysis on the reasonableness of Halifax’s FMV methodology under the Stark Law. With respect to the Neurosurgeons, the United States’ FMV

¹ The Physicians are neurosurgeons Drs. Rohit Khanna, William Kuhn, and Federico Vinas (the “Neurosurgeons”); medical oncologists Drs. Boon Chew, Ruby Anne Deveras, Walter Durkin, Gregory Favis, Abdul Sorathia, Richard Weiss (the “Medical Oncologists”), and gynecological surgeon Dr. Kelly Molpus.

expert, Ms. Kathy McNamara, cannot raise a material dispute of fact regarding the reasonableness of Halifax's FMV methodology because she ignored the law and the testimony of the United States' own 30(b)(6) witness, Troy Barsky, and substituted her own FMV assessment methodology for Halifax's in order to justify her own conclusions. Further, Halifax is entitled to summary judgment because the United States cannot offer evidence that any term of the Neurosurgeons' agreements is illegal or were negotiated, implemented, or paid in anything less than good faith compliance with the Stark Law. Without such evidence, the United States cannot carry its FCA burden to show Halifax knowingly submitted false Medicare claims.

Halifax is also entitled to summary judgment with respect to the Medical Oncologist claims because the United States did not provide an expert opinion on either FMV or commercial reasonableness for the Medical Oncologists' compensation. Halifax staff who negotiated the Medical Oncologists' contracts testified unequivocally the contracts were FMV, any bonuses paid were based upon each Medical Oncologist's personally performed services, they believed the strategy of directly employing physicians was commercially reasonable, compensation was determined by market conditions and Halifax's budget constraints, not by actual or anticipated referrals, and the underlying rationale for the compensation structure was to retain the best physicians at the lowest cost based on market conditions. In opposition, the United States relies solely on an illogical reading of the *Bona Fide* Employment Exception to justify its allegations.

Moreover, all of the United States' FCA claims must fail given the vagueness and ambiguity of the Stark Law. The United States cannot demonstrate a material dispute of fact exists as to the alleged falsity of the claims, or that Halifax acted knowingly in submitting any false claims to the United States. The evidence shows Halifax implemented the incentive bonus for the Medical Oncologists for Fiscal Year 2005 after a good faith, deliberative process,

including an advance, substantive review and approval by the General Counsel, and continued without issue during Fiscal Years 2006 and 2007. After Relator raised a concern, and before paying the bonus for Fiscal Year 2008, Halifax sought legal advice from competent outside counsel that confirmed the incentive bonus complied with the *Bona Fide* Employment Exception. That counsel for the United States, but no Stark Law expert testifying on its behalf, has a different interpretation of the requirements of the *Bona Fide* Employment Exception is further evidence that Halifax could not have acted knowingly when submitting Medicare or Medicaid claims.

Moreover, the United States' Complaint in Intervention ("Complaint") includes Dr. Kelly Molpus, an employed gynecological surgeon, but it cannot offer any evidence to rebut the fact Dr. Molpus never received any incentive bonus payments. Summary judgment is warranted for any Halifax claims identified by the United States for any services associated with Dr. Molpus.

Last, due to the absence of evidence supporting Causes of Action One through Three, the United States' common law Causes of Action Four through Six must also be dismissed.

II. STATEMENT OF MATERIAL FACTS AND ALLEGATIONS

Halifax is a community hospital owned by the District,² and is organized under the laws of the state of Florida as a special taxing district created pursuant to an act of the Florida Legislature. *See* 1979 Fla. Laws 577. Halifax provides comprehensive care to the local service area through a network of organizations including a 764-bed hospital with the only Level II Trauma Center in Volusia and Flagler Counties. Consistent with Florida law, including 2003-374, Laws of Florida, and Chapter 768, Florida Statutes, the District created Halifax Staffing, a not-for-profit Florida corporation, which leases the individuals who staff the District's health care

² Halifax Hospital Medical Center is a community hospital owned by the residents of the Halifax Special Taxing District (the "District"). They are one and the same. Halifax Staffing is an instrumentality of the District.

facilities. The District is governed by a Board of Commissioners appointed by the Governor of Florida. *See* Chapter 2003 Fla. Laws 374.

Halifax is the principal charity care provider serving Volusia and Flagler Counties. As one of only 14 member hospitals in Florida's Safety Net Hospital Alliance, Halifax treats all patients who come to its Emergency Department regardless of their ability to pay.³ In 2009, Halifax provided \$76.8 million in community benefits, including uncompensated care to the uninsured, trauma services, and neonatal and pediatric services. *See* Ex. 1 Halifax Health Community Benefits Factsheet.⁴ In 2011, Halifax handled over one-third of all admissions in Volusia County – over 23,000. Ex. 2 Volusia County, Florida Hospital Admissions, Calendar Year 2011, *available at*: www.floridahealthfinder.gov.

Halifax provides significant charity-based cancer care. Since charity care is not as lucrative as private practice, many local medical oncologists have elected to enter private practice so as to avoid charity care patients. Ex. 3, Durkin Dep., at 43:5-44:12. As a result, Halifax serves as the safety net provider for cancer patients. Ex. 3, Durkin Dep., at 43:12-19.

Halifax has employed three neurosurgeons, Dr. Khanna, Dr. Kuhn, and Dr. Vinas, since July 7, 2001; February 14, 2003; and July 10, 2000, respectively. Ex. 4, Khanna Decl., ¶ 2; Ex. 5, Kuhn Decl., ¶ 2; Ex. 6, Vinas Decl., ¶ 2. Halifax developed a compensation structure that provides each Neurosurgeon with a base salary plus an incentive bonus equal to the collections for each Neurosurgeon's personally performed services if he exceeds his base salary. The United States alleges that the Neurosurgeons' compensation is excessive and that Halifax submitted

³ *See* Safety Net Hospital Alliance of Florida – Member Hospitals, publicly available at <http://safetynetsflorida.org/member-hospitals>.

⁴ Halifax Health Community Benefits Factsheet, publicly available at <http://extranet.acsysweb.com/vsitemanager/Halifax/Public/Upload/SubmittedDocuments/0309-0679%20Community%20Benefits%202012.pdf>.

false claims throughout the tenure of each employed Neurosurgeon.

During the relevant time period, Halifax has employed six Medical Oncologists. Dr. Boon Chew, Dr. Walter Durkin, Dr. Gregory Favis, Dr. Abdul Sorathia, and Dr. Richard Weiss were all employed by Halifax when the March 1, 2004 compensation agreements became effective. Dr. Ruby Anne Deveras joined Halifax effective August 23, 2005. Ex. 7, Chew Decl., ¶ 2; Ex. 8, Deveras Decl., ¶ 2; Ex. 9, Durkin Decl., ¶ 2; Ex. 10, Favis Decl., ¶ 2; Ex. 11, Sorathia Decl., ¶ 2; Ex. 12, Weiss Decl., ¶ 2. Beginning March 1, 2004, Halifax's agreements with these physicians provided a modest base salary of \$135,000 and two productivity bonuses that Halifax distributed based exclusively on each Medical Oncologist's personally performed services. Ex., 13, Medical Oncology Employment Agreement. Beginning Fiscal Year 2005, Halifax slightly modified the composition of one bonus pool. Halifax calculated the new bonus pool based on 15% of the operating margin of the Medical Oncology Program. The allocation of the bonus pool was, however, still based on each physician's personal productivity. The United States alleges Halifax improperly billed Medicare for medical oncology claims from 2004 through 2010, but only alleges Stark Law violations for the bonuses paid for Fiscal Years 2005 through 2008.

III. SUMMARY JUDGMENT LEGAL STANDARD

"Under Rule 56(c), summary judgment is proper if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986) (internal quotation marks omitted). "Summary judgment is appropriate when the evidence, viewed in the light most favorable to the nonmoving party, presents no genuine issue of material fact and compels judgment as a matter of law in favor of the moving party." *Holloman v. Mail-Well Corp.*, 443 F.3d 832, 836–37 (11th Cir. 2006).

Which facts are material depends on the substantive law applicable to the case. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). The moving party bears the burden of showing that no genuine issue of material fact exists. *Clark v. Coats & Clark, Inc.*, 929 F.2d 604, 608 (11th Cir.1991). When a party moving for summary judgment points out an absence of evidence on a dispositive issue for which the non-moving party bears the burden of proof at trial, the nonmoving party must “go beyond the pleadings and by [his] own affidavits, or by the depositions, answers to interrogatories, and admissions on file, designate specific facts showing that there is a genuine issue for trial.” *Celotex Corp.*, 477 U.S. at 324 (internal quotations and citation omitted). Thereafter, summary judgment is mandated against the nonmoving party who fails to make a showing sufficient to establish a genuine issue of fact for trial. *Id.* at 322, 324-25; *see also Shurick v. Boeing Co.*, No. 6:07-cv-1974-Orl-31GJK, 2010 WL 258788, at *1-2 (M.D. Fla. Jan. 20, 2010), *aff’d*, 623 F.3d 1114 (11th Cir. 2010).

Under FCA jurisprudence, summary judgment is proper when the party opposing summary judgment fails to provide evidence rebutting affidavits or other evidence presented by the movant explicitly denying certain required elements of the FCA. *See United States ex rel. Kaimowitz v. Ansley*, 250 Fed. Appx. 912, 915 (11th Cir. 2007) (affirming summary judgment, stating, “The Defendants filed affidavits from various individuals explicitly denying the presentation of a false claim to the United States with regard to the transactions surrounding the Boca Club project. Kaimowitz filed nothing in opposition.”).

IV. LEGAL FRAMEWORK

A. The Stark Law

The Stark Law contains a two-part prohibition: (i) a physician may not make a referral to an entity for the furnishing of DHS if the physician has a “financial relationship” with the entity (the “Referral Prohibition”); and (ii) an entity may not submit a claim to Medicare or bill any

party for DHS furnished as a result of a prohibited referral (the “Billing Prohibition”).⁵ 42 U.S.C. § 1395nn(a)(1)(A)-(B). CMS defines a “referral” as “the request by a physician for, or ordering of, or the certifying or recertifying of the need for, any [DHS] ... or a request by a physician that includes the provision of any [DHS] for which payment may be made under Medicare, [or] the establishment of a plan of care” 42 C.F.R. § 411.351.

A “financial relationship” is, *inter alia*, a “direct or indirect compensation arrangement . . . with an entity that furnishes DHS. 42 C.F.R. § 411.354. A direct compensation arrangement exists if “remuneration passes between the referring physician . . . and the entity furnishing DHS without any intervening persons or entities.” 42 C.F.R. § 411.354(c)(1). An employer that has a direct compensation arrangement with a physician may pay incentive compensation that complies with the *Bona Fide* Employment Exception.

Under the *Bona Fide* Employment Exception, an entity may pay the following:

Any amount paid by an employer to a physician (or an immediate family member of such physician) who has a bona fide employment relationship with the employer for the provision of services if—

- (A) the employment is for identifiable services,
- (B) the amount of the remuneration under the employment—
 - (i) is consistent with the fair market value of the services, and
 - (ii) is not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician,
- (C) the remuneration is provided pursuant to an agreement which would be commercially reasonable even if no referrals were made to the employer, and
- (D) the employment meets such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse.

Subparagraph (B)(ii) shall not prohibit the payment of remuneration in the form of a productivity bonus based on services performed personally by the physician (or

⁵ CMS has identified an exhaustive list of Designated Health Services. Ex. 14, 42 C.F.R. § 411.351.

an immediate family member of such physician).

42 U.S.C. § 1395nn(e)(2).

The *Bona Fide* Employment Exception does not require compensation to be set in advance. Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II), 69 Fed. Reg. 16,054, 16,067 (Mar. 26, 2004). Further, personally performed services do not constitute "referrals." 42 C.F.R. § 411.357(c); 69 Fed. Reg. at 16,067.

B. The False Claims Act

The United States alleges violations of Sections 3729(a)(1), (2), and (7) of the FCA. To establish a cause of action under the FCA, a plaintiff must prove three elements: (1) a false or fraudulent claim; (2) which was presented, or caused to be presented, by the defendant to the United States for payment or approval; (3) with the knowledge that the claim was false.

Kaimowitz, 250 Fed. Appx. at 915 (citing *United States ex rel. Walker v. R&F Properties of Lake Cnty., Inc.*, 433 F.3d 1349, 1355 (11th Cir. 2005)).

To establish a violation of Section 3729(a)(1), the United States must prove: (1) Halifax presented or caused to be presented to the government a claim for payment; (2) the claim was false or fraudulent; and (3) Halifax knew it was presenting a false or fraudulent claim for payment. *See United States ex rel. Stinson v. Provident Life & Accident Ins. Co.*, 721 F. Supp. 1247, 1258-59 (S.D. Fla. 1989); *United States ex rel. Watson v. Connecticut Gen. Life Ins. Co.*, Civ. No. 98-6698, 2003 U.S. Dist. LEXIS 2054, at *13-16 (E.D. Pa. Feb. 11, 2003); *United States ex rel. Wilkins v. North Am. Construction Corp.*, 173 F. Supp. 2d 601, 618-19 (S.D. Tex. 2001). Section 3729(a)(2) requires proof that: (1) Halifax made or caused to be made a record or statement to get a claim against the United States paid; (2) the record or statement and the claim were false or fraudulent; and (3) Halifax knew the record or statement and the claim were false or fraudulent. *See Stinson*, 721 F. Supp. at 1259; *United States v. Warning*, Civ. Action No. 93-

4541, 1994 U.S. Dist. LEXIS 10402, at *10-11 (E.D. Pa. July 26, 1994). Knowing means, with respect to information, a person (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information. 31 U.S.C. § 3729(b).

Imprecise statements or a difference in interpretation growing out of a disputed legal question are not false under the FCA. *See, e.g., United States ex rel. Parato v. Unadilla Health Care Ctr., Inc.*, 787 F. Supp. 2d 1329, 1339 (M.D. Ga. 2011); *see also United States ex rel. Lamers v. City of Green Bay*, 998 F. Supp. 971, 986 (E.D. Wis. 1998) (same). Innocent mistake and mere negligence cannot form the basis for FCA liability. *See United States ex rel. Hochman v. Nackman*, 145 F.3d 1069, 1074 (9th Cir. 1998); *United States v. Taber Extrusions, LP*, 341 F.3d 843, 845 (8th Cir. 2003); *United States v. Southland Mgmt. Corp.*, 326 F.3d 669, 681 (5th Cir. 2003) (Jones, J., Concurring); *United States ex rel. Durcholz v. FKW Inc.*, 189 F.3d 542, 544 (7th Cir. 1999); *Hindo v. Univ. of Health Sciences*, 65 F.3d 608, 613-14 (7th Cir. 1995); *United States v. Medica-Rents Co.*, 285 F. Supp. 2d 742, 771 (N.D. Tex. 2003), *aff'd in part, rev'd in part*, 2008 U.S. App. LEXIS 17946 (5th Cir. 2008) (“Merely submitting a false claim does not show the necessary scienter for fraud.”); *Watson*, 2003 U.S. Dist. LEXIS 2054, at *16. The requisite scienter is the “knowing presentation of what is known to be false.” *Id.*

V. LEGAL ARGUMENT REGARDING FIRST CAUSE OF ACTION ALLEGING VIOLATION OF THE STARK LAW AND 31 U.S.C. §§ 3729(a)(1) and (a)(1)(A)

The Physicians’ agreements do not, factually or as a matter of law, violate the Stark Law because they meet the requirements of the *Bona Fide* Employment Exception set forth in Section (IV)(A). There is no material dispute of fact the Physicians’ agreements are direct compensation arrangements that provide FMV compensation, are commercially reasonable, and do not impermissibly take into account the volume or value of referrals to Halifax.

Each Physician received a fixed base salary and productivity bonus(es) based on his or her personally performed services, which is what the law requires. The United States' FMV/commercial reasonableness expert, Ms. McNamara, shirked her responsibility to perform a reasonableness analysis of Halifax's FMV assessment methodology.

The United States also cannot carry its burden to offer credible evidence identifying prohibited "referrals" made by the Physicians. The United States' damages rely solely on Medicare claim forms that include many claims for categories of services that, as a matter of law, are not referrals. Ex. 15, Dew Dep., at 148:12-149:4. Halifax provides undisputed evidence as to why patient medical records, not Medicare claim forms, are the only credible evidence for establishing whether a prohibited referral was made, and by whom. The United States could have used patient records to identify referrals but chose not to obtain these records despite repeated requests by Halifax. Ex. 31, First Set of Reqs. for Production from the United States (Feb. 27, 2012). To the extent the United States asserts that the Physicians' agreements were indirect compensation arrangements, there is no dispute of fact the agreements also satisfy the indirect compensation arrangement exception.

A. The Neurosurgeon Contracts Are Direct Compensation Arrangements That Comply With The *Bona Fide* Employment Exception

The United States' case is shockingly devoid of evidence about the compensation market for neurosurgeon services. As set forth by Halifax's FMV/commercial reasonableness expert, the market for neurosurgeons is a highly competitive, national market suffering from a shortage. Ex. 16, O'Brien Rep., at 32. Halifax recruited the Neurosurgeons under these market conditions using reasonable criteria for a Level II Trauma Center in a small, regional market. Ex. 17, Peburn Dep., at 110:22-111:18. The United States' FMV expert ignored the law and the testimony of the United States' own 30(b)(6) witness, Troy Barsky, a CMS employee testifying on the United

States' interpretations of FMV and commercial reasonableness. *See, e.g.*, Ex. 18, McNamara Dep., at 26:1-4. Instead of performing a reasonableness analysis of Halifax's FMV methodology, Ms. McNamara substituted, *de novo*, her own FMV methodologies in order to justify her conclusions. Ms. McNamara also testified that she excluded from her report her findings that some criteria used by Halifax were commercially reasonable. Ex. 19, McNamara Dep., at 120:11-121:17; 171:4-172:6. Mr. Barsky's testimony makes clear the arbitrary, substitute criteria relied upon by Ms. McNamara for her Neurosurgeon analysis do not have any basis in the United States' Stark Law policy, statutes, or regulations.

1. There Is No Material Dispute Of Fact That The Neurosurgeon Arrangements Are Direct Compensation Arrangements

There is no material dispute of fact that Halifax's Neurosurgeon agreements constitute direct compensation arrangements subject to the *Bona Fide* Employment Exception. The Stark Law defines "employee" as "any individual who, under the common law rules that apply in determining the employer-employee relationship (as applied for purposes of section 3121(d)(2) of the Internal Revenue Code of 1986), is considered to be employed by, or an employee of, an entity." 42 C.F.R. § 411.351; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships, 66 Fed. Reg. 856, 946 (Jan. 4, 2001); Ex. 20, Barsky Dep., at 180:20-181:19. Thus, if the relationship between an entity and a particular physician meets the employment test adopted by the Internal Revenue Service ("IRS"), the physician is considered an employee of that entity for purposes of the Stark Law.

Under the IRS test, a common law employer-employee relationship exists when the person for whom services are performed has the right to "control and direct the individual who performs the services, not only as to the result to be accomplished by the work but also as to the details and means by which that result is accomplished." Treas. Reg. § 31.3121(d)-1(c)(2). The

IRS uses 20 non-exclusive factors to determine the existence of an employment relationship. Ex. 21, Rev. Rul. 87-41, 1987-1 C.B. 296, 298-99; *see also James v. Comm'r*, 25 T.C. 1296 (1956) (finding a pathologist was a hospital employee because of the integration of his work to the hospital and community need for his services). The Eleventh Circuit has adopted the IRS' 20-factor test for an analysis of an employee's status. *Hosp. Res. Pers. v. United States*, 68 F.3d 421, 427 (11th Cir. 1995) (citing Rev. Rul. 87-41, 1987-1 C.B. 296). The IRS uses the 20-factor test to analyze "the employee status of physicians practicing medicine in a hospital setting." Ex. 22, I.R.S. Proposed Coordinated Issue Paper, Employee Status of Hospital-Based Physicians and on Student Nurse Exclusion from Definition of Employment (Mar. 26, 1993) (the "Proposed Coordinated Issue Paper"). The IRS focuses on "whether the institution has the right to direct and control the manner and means of the business aspects of the physician's medical practice."

Id. CMS states:

... the actual conduct of the relationship is determinative. To determine whether an employer-employee relationship exists, the various factors, including those regarding supervision, used by the Internal Revenue Service (IRS) to determine employee status apply. Whereas the receipt of a W-2 from an entity and the written terms of the arrangement are relevant, neither controls whether an individual meets the definition of "employee" for purposes of the physician self-referral law; rather, the focus is on the actual relationship between the parties.

Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase III), 72 Fed. Reg. 51,012, 51,014 (Sept. 5, 2007).

Under the IRS test, Halifax is the Neurosurgeons' employer for Stark Law purposes. Halifax sets the budget for the neurosurgery department and bills Medicare and private payers for Neurosurgeon services. The Neurosurgeons must comply with all medical staff bylaws, and Halifax manages their practices. Ex. 23, Peburn Dep., at 271:23-273:3. Halifax – through the hospital's chief of staff and its Board of Directors – has ultimate oversight over these physicians. Ex. 24, Peburn Dep., at 279:6-281:20. The Neurosurgeon services have been fully integrated into

Halifax's services, with all services performed on Halifax's campus. Ex. 25, Dr. Khanna Dep., at 16:10-23. In addition, Halifax pays for certain business expenses, including continuing medical education, computer hardware and software, and office furniture. Ex. 26, Vinas Dep., at 39:17-41:11. Indeed, the Physicians believe Halifax is their employer. *See, e.g.*, Ex. 27, Khanna Dep., at 11:18-24.

Halifax Staffing is merely an alter ego of Halifax established to enable Halifax to move its employees from the Florida state retirement system into a self-funded retirement program. Ex. 29, Peburn Dep., at 122:7-123:6. The IRS confirmed in a 1995 ruling letter obtained in connection with the creation of Halifax Staffing that the entity is an instrumentality of Halifax. Ex. 30, IRS Ruling Letter; Ex. 23, Peburn Dep., at 271:25-272:5. Halifax Staffing has no board of its own, instead sharing Halifax's Board of Commissioners. Ex. 32, Peburn Dep., at 238:4-21. Halifax Staffing's only bank account is a zero-balance sweep account funded solely through direct transfers from Halifax's bank accounts in order to satisfy employee payroll. Ex. 33, Halifax Staffing Bank Account Info.; Ex. 23, Peburn Dep., at 272:6-13. Moreover, CMS has expressly stated leased employees may qualify as *bona fide* employees under the relevant tests: "to the extent that a leased employee is a bona fide employee of the DHS entity under IRS rules, remuneration paid to that employee would be eligible under the [*bona fide* employment] exception." 69 Fed. Reg. at 16,087.

The United States' evidence to the contrary is superficial. Payment of employee salaries, issuance of W-2 tax forms and the fact that several of the Physicians' agreements identify Halifax Staffing as the counterparty are insufficient to establish Halifax Staffing as the Physicians' employer. The Court should find as a matter of law that the totality of the factors shows that the Neurosurgeons are Halifax employees.

2. **Halifax's Compensation Arrangements With The Neurosurgeons Comply With The *Bona Fide* Employment Exception.**

a. The Compensation Is Fair Market Value

(i) A Provider May Use Any Reasonable Method To Determine FMV In Compliance With The Stark Law

It is undisputed that CMS is prohibited from opining on FMV and accepts “any method that is commercially reasonable and provides [CMS] with evidence that the compensation is comparable to what is ordinarily paid for an item or service in the location at issue, by parties in arm’s length transactions who are not in a position to refer to one another.” 66 Fed. Reg. at 944. The United States’ 30(b)(6) witness confirmed this. Ex. 34, Barsky Dep., at 65:17-66:16. The United States’ FMV expert agreed that a provider may use “any method that is commercially reasonable.” Ex. 35, McNamara Dep., at 161:11-162:13. CMS does not require independent valuations by outside consultants. 66 Fed. Reg. at 945. Accordingly, the appropriate inquiry is whether Halifax used a reasonable methodology to conduct its FMV review, not whether the United States’ expert could come to the opposite conclusion using her own FMV methodology. 66 Fed. Reg. at 944 (“The burden of establishing the ‘fairness’ of an agreement rests with the parties involved in the agreement.”).

Halifax’s process complied with the widely discretionary FMV guidance published by CMS. As stated by Halifax’s expert, Kevin O’Brien, the test is whether the compensation is justified by the level of productivity of the physician. Ex. 16, O’Brien Rep., at 12. Mr. Barsky testified that third-party comparative salary survey “percentiles” are irrelevant to FMV, and that CMS assigns no weight to whether compensation falls within the 50th, 75th, or 90th percentile of any third-party comparative survey. Ex. 36, Barsky Dep., at 82:4-86:22.

Halifax has always analyzed the FMV of each physician contract. Ex. 37, Peburn Dep., at 31:4-13; Ex. 38, Lang Dep., at 19:11-20:5; Ex. 39, Rousis Dep. (Nov. 1, 2012), at 251:4-18; Ex.

40, Rousis Dep. (Feb. 20, 2013), at 32:6-37:17. Mr. Barsky testified that while parties should “consider” obtaining written assurances, the presence of a writing regarding FMV is not required. 66 Fed. Reg. at 966; Ex. 41, Barsky Dep., at 69:1-71:2. Halifax employees used third-party compensation data from sources including Medical Group Management Association, Sullivan, Cotter & Associates, and Estes and Associates in negotiating physician agreements. Ex. 42, Peburn Dep., at 38:12-39:8, 46:21-47:7; Ex. 38, Lang Dep., at 19:11-20:5. In Stark Law preamble guidance, CMS has previously deemed various third-party survey sources as reliable for this purpose. 69 Fed. Reg. at 16,128.

Halifax is the only Level II Trauma Center in its region, so it reviewed compensation data from other Level II Trauma Centers when negotiating the Neurosurgeons’ employment agreements and amendments. Ex. 44, Peburn Dep., at 38:12-39:8, 67:5-9, 103:4-17; Ex. 38, Lang Dep., at 19:11-20:5; Ex. 45, Cason Dep., at 32:22-33:3. CMS agrees with this approach where there are no local comparables. 66 Fed. Reg. at 944. The Legal Department reviewed each agreement, including the terms of the financial arrangements, to ensure they complied with the FMV criterion of the *Bona Fide* Employment Exception. Ex. 46, Peburn Dep., at 67:20-69:22; Ex. 47, Halifax Compliance Standards No. LL-101; Ex. 45, Cason Dep., at 32:19-33:6. Further, Halifax had procedures in place to regularly reassess the terms of the physician contracts because of the competitive markets for specialty physicians. Ex. 43, Peburn Dep., at 40:21-41:8.

(ii) Halifax’s Neurosurgeon Compensation Was FMV

Each time Halifax looked at comparables and the third-party compensation data, it concluded the compensation was FMV based on their high productivity, significant levels of

charity care, and the call coverage they provided for the Level II Trauma Center.⁶ *See, e.g.*, Ex. 6, Vinas Decl. Halifax knew similar trauma centers paid substantially more than Halifax for call coverage. Ex. 48, Lang Dep., at 149:17-150:11. Halifax's expert, Mr. O'Brien, analyzed the compensation per relative value unit of work ("wRVU"),⁷ a measurement of productivity CMS has adopted to assess the relative level of time, skill, training, and intensity of a procedure. Ex. 16, O'Brien Rep., at 12. The compensation per wRVU methodology correlates compensation to productivity. Ex. 16, O'Brien Rep., at 12; Ex. 49, McNamara Rep., at 10. Mr. O'Brien concluded each Neurosurgeon's compensation was FMV based on his productivity.

In response to assertions that the Neurosurgeons' productivity was suspect, Mr. O'Brien took the additional step of assuming, *arguendo*, all of the billing and coding allegations raised by the United States' expert were true. Ex. 16, O'Brien Rep., at 13-16. For all of the CPT codes associated with the allegations, Mr. O'Brien substituted an average wRVU for the wRVUs reported by each Neurosurgeon.⁸ *Id.* at 14. This step eliminated any impact of the allegations on the Neurosurgeon's overall productivity. *Id.* Mr. O'Brien's conclusions did not change. *Id.* at 19.

Mr. O'Brien also assessed the accuracy of the Neurosurgeons' surgical logs. Ex. 51, O'Brien Dep., at 254:19-255:2. In doing so, he verified that "the neurosurgeons completed their surgeries in significantly less time than suggested in the CMS Physician Time File."⁹ Ex. 16, O'Brien Rep., at 17. The Neurosurgeons simply work longer and more efficiently than the average physician. Ex. 52, Lewis Dep., at 54:5-9; Ex. 53, Vinas Dep., at 127:21-128:2. Halifax's

⁶ Halifax also considered these comparables when determining the appropriate payment for the call coverage and trauma services the Neurosurgeons provide. Ex. 50, Lewis Dep., at 47:15-48:24.

⁷ A unique wRVU is assigned to each Current Procedural Terminology (CPT[®]) code, which is used to report procedures.

⁸ Mr. O'Brien assumed an average level of productivity for these codes based upon an expected distribution for neurosurgeons in Florida. Ex. 16, O'Brien Rep., at 15.

⁹ The CMS Physician Time File contains time averages per CPT code based on physician surveys. <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1590-FC.html?DLPage=1&DLSort=3&DLSortDir=descending>.

Neurosurgeons are high wage earners. However, their income is consistent with the range of publicly available tax data from other non-profit hospitals, as compiled by Halifax's FMV expert. Ex. 54, Neurosurgeon Compensation at Not-For-Profit Entities. Several neurosurgeons on the chart earn substantially more than the Neurosurgeons. *Id.* Ms. McNamara's report also summarizes the Neurosurgeons' annual compensation for the relevant years and shows their compensation falls within the appropriate range. Ex. 49, McNamara Rep., at 4.

(iii) The United States Cannot Produce Any Credible Evidence That Halifax's FMV Methodology Was Unreasonable

The United States cannot offer credible expert testimony establishing that Halifax's FMV methodology was unreasonable. Ms. McNamara did not reach any conclusions in her report about the reasonableness of Halifax's FMV methodology. Her report reflects only her personal opinions about the terms of the compensation arrangements, instead of any actual step-by-step analysis of how Halifax performed its FMV assessment. *See generally United States ex rel. Samuel L. Armfield, III, and Patricia Armfield v. James P. Gills, et al.*, Case No. 8:07-cv-2374-T-27TBM, 2012 U.S. Dist. LEXIS 154749 (M.D. Fla. Oct. 29, 2012) (finding that in order to defeat summary judgment, the party must submit an expert report).

Ms. McNamara's report often directly conflicts with Mr. Barsky's 30(b)(6) testimony on FMV. Ms. McNamara testified she did not use – or even review – CMS policies or statements about FMV methodologies when developing her report. Ex. 55, McNamara Dep., at 41:11-42:7. Nor did she even know about or take into account Mr. Barsky's testimony, taken three months before her report was submitted on December 21, 2012. Ex. 56 McNamara Dep., at 26:1-27:11, 35:22-36:20, 39:15-22. Ms. McNamara testified “[t]ypically when I have done such reports, I have not reviewed the deposition testimony of CMS representatives . . . I have felt -- I didn't feel it was necessary, because I feel I have a good level of understanding and expertise in the subject

matter.” Ex. 56, McNamara Dep., at 36:11-20. Mr. Barsky stated parties to an agreement are responsible for determining FMV, but Ms. McNamara ignored his testimony while agreeing his statement could be relevant to her conclusions. Ex. 57, McNamara Dep., at 39:10-42:12.

To the extent Ms. McNamara performed an analysis, she did not offer benchmarking data from comparable Level II Trauma Centers to counter Halifax’s fact witness and expert testimony, or discuss how her FMV methodologies reflect – or even take into consideration – the guidance published by CMS. Ex. 58, McNamara Dep., at 392:16-393:4. Instead, Ms. McNamara reached outside her area of expertise to insinuate the Neurosurgeons faked their productivity through three schemes for which she has done no independent analysis or investigation. Ex. 59, McNamara Dep., at 288:5-19; 296:7-22. Ms. McNamara, a certified public accountant, not a clinician, opined that the Neurosurgeons’ compensation was inflated because (i) Dr. Vinas allegedly conducted medically unnecessary surgeries; (ii) Dr. Khanna and Dr. Vinas allegedly improperly billed for services performed by certain medical assistants; and (iii) Dr. Khanna allegedly improperly coded certain procedures. Ex. 49, McNamara Rep., at 20-24.

None of these allegations have any credible support, and Ms. McNamara’s report is devoid of any actual analysis of how these allegations, even if true, would materially impact the Neurosurgeons’ productivity data. Ex. 60, McNamara Dep., at 306:16-307:14. As set forth in Section (2)(a)(ii), Halifax’s expert verified the accuracy of the Neurosurgeons’ wRVUs, while Ms. McNamara did not undertake the same steps. Other Halifax experts, Dr. Schoettle and David Yarin, examined the clinical medical necessity and the statistical relevance of the United States’ evidence, the AllMed Report. Mr. Yarin concluded the AllMed Report was not credible because the process was not consistent with Halifax’s peer review process. Ex. 61, Yarin Rep., at 5. Relator admitted to cherry-picking the cases forming the sample, admitted the sample was not

statistically valid or representative, and failed to ensure the AllMed reviewers received complete medical records. Ex. 61, Yarin Rep., at 6; Ex. 62, Relator Dep., at 114:7-120:12. Moreover, the AllMed Report neither identified the reviewers' qualifications nor the medical necessity criteria used to reach their conclusions. Ex. 61, Yarin Rep., at 7. Dr. Schoettle performed an independent review of the complete medical record for each case in the AllMed Report and determined all of Dr. Vinas' procedures were medically necessary and surgically sound. Ex. 63, Schoettle Rep., at 3-16. The United States does not dispute Dr. Schoettle's or Mr. Yarin's findings.

Based on her failure to perform the proper analysis of Halifax's FMV methodology and her disregard of the United States' 30(b)(6) testimony, this Court should disregard any FMV opinions in Ms. McNamara's report.

b. Halifax Had A Commercially Reasonable Rationale For The Neurosurgeon Agreements

The Neurosurgeon agreement terms were commercially reasonable. CMS allows the parties to an agreement to use "any reasonable method of valuation" to arrive at commercially reasonable terms, and accords wide latitude to the parties. 66 Fed. Reg. at 919; Ex. 64, Barsky Dep., at 38:12-39:2, 40:1-17, 41. According to CMS' vague guidance, a commercial reasonableness analysis must assess whether the agreement would make commercial sense for a "reasonable entity of similar type and size and a reasonable physician . . . of similar scope and specialty" in the absence of referrals. 69 Fed. Reg. at 16,093.

Halifax's expert testified hospitals must consider whether the arrangement is reasonable given the availability of specialty physicians; the trauma designation of the hospital; the need to provide indigent care; and the need for the hospital to succeed in its mission. Ex. 65, O'Brien Dep., at 80:3-11. Halifax's other commercial reasonableness expert testified that "the projected physician supply needs relative to a population that's within a defined service area." Ex. 66,

Vance Dep., at 86:9-11; *see also* Ex. 67, Vance Rep., at 5. Ms. McNamara agreed that the analysis must assess whether “there is a particular specialty that is not prevalent or not available in the community” Ex. 68, McNamara Dep., at 72:22-73:14. Halifax did exactly that in determining commercially reasonable compensation for its Neurosurgeons.

The evidence shows Halifax identified an unmet community need for neurosurgical call coverage and undertook to fill this need despite a widely known nationwide neurosurgeon shortage. Ex. 69, Peburn Dep., at 82:4-83:10, 110:20-113:5, 118:2-8.¹⁰ As a Level II Trauma Center, Florida requires Halifax to have a neurosurgeon available at all times.¹¹ This is an onerous obligation on on-call Neurosurgeons to stay within reach of the hospital, and required Halifax to consider this burden when negotiating with the Neurosurgeons. Ex. 50, Lewis Dep., at 47:15-48:3. Ms. McNamara’s commercial reasonableness opinion gives no consideration to the special staffing obligations of a “reasonable entity of similar type and size,” *i.e.*, another Level II Trauma Center. Ex. 70, *Id.* at 229:5-14. Yet in her testimony, she admitted to intentionally excluding from her report her conclusion that it was commercially reasonable for Halifax to employ the Neurosurgeons to provide call coverage. Ex. 71, McNamara Dep., at 121:10-17.

The United States’ commercial reasonableness argument is based on the flawed and unsupported position it is commercially unreasonable for a hospital to run unprofitable physician practices. Ms. McNamara asserted it “does not make sense from a business prospective [sic]” to pay a bonus of 100 percent of cash collections after recovering the base salary. Ex. 49, McNamara Rep., at 28. Ms. McNamara’s testimony contradicted her report: “I’m not stating that it’s commercially unreasonable to incur a loss. Hospitals do incur losses at various

¹⁰ Gottfried, ON, Rovit RL et al. Neurosurgical workforce trends in the United States. *J. Neurosurgery*. 102:2 (2005). *See also* Ex. 16, O’Brien Rep., at 31-32.

¹¹ Fl. Dep’t Health, Trauma Center Standards, chpt. 3, Standard III(B) (Jan. 2010), *available at* <http://www.doh.state.fl.us/demo/trauma/PDFs/TraumaCntrStandDOHPamphlet150-9-2009rev1-14-10-FinalVer.pdf>.

departments.” Ex. 72, McNamara Dep., at 221:22-222:2. She also testified recently at trial as an expert that it can be commercially reasonable to pay a specialist more money than they collect. Ex. 73, McNamara Tuomey testimony, Trial Transcript (Apr. 24, 2013), 36:24-37:2. In addition, the United States’ 30(b)(6) not-for-profit witness, Dr. Daniel Duvall, testified CMS does not have any policy requiring a hospital service line to be profitable, underscoring the arbitrary and contradictory criteria Ms. McNamara employed. Ex. 74, Duvall Dep., at 46:10-47:3.

Ms. McNamara’s analysis ignored the financial burden to Halifax of the extensive charity care the Neurosurgeons provided. Charity care meets a community need, and the Neurosurgeons should be compensated for non-revenue-generating patient care. Ex. 75, Peburn Dep., at 141:13-143:19. Halifax reasonably considered a physician’s obligation to provide substantial charity care when negotiating the Neurosurgeons’ agreements. Ex. 76, Peburn Dep., at 103:12-17; Ex. 77, Henley Letter. The IRS has agreed it is appropriate for non-profit hospitals to compensate physicians for treating charity care patients. *See* Revenue Ruling 97-21, 1997-1, C.B. 121.

c. The Incentive Compensation For The Neurosurgeons Was A Permissible Productivity Bonus

As shown in Section IV(A), the *Bona Fide* Employment Exception expressly permits the Neurosurgeons’ productivity bonuses. There is no evidence the compensation arrangements take into account the volume or value of referrals to Halifax because the productivity bonuses were based solely on the services that each Neurosurgeon personally performed. Moreover, CMS agrees the productivity bonuses are proper *even if* there is a corresponding DHS associated with the personally performed service (*e.g.*, a facility fee). 69 Fed. Reg. at 16,088-89.

B. **The Medical Oncologists’ Contracts Are Direct Compensation Arrangements Complying With The *Bona Fide* Employment Exception**

The *Bona Fide* Employment Exception expressly permits the personal productivity

bonuses that were paid to the Medical Oncologists, and the United States has not offered any evidence to suggest that the compensation arrangements with the Medical Oncologists fail to meet the other requirements of the *Bona Fide* Employment Exception. The United States asserts the operating margin bonus constitutes impermissible compensation, despite the undisputed fact this bonus is a productivity bonus based on each Medical Oncologist's personally performed services. With respect to FMV and commercial reasonableness, the United States elected not to obtain any expert opinion on the Medical Oncologists' agreements. Halifax is entitled to judgment as a matter of law that the compensation arrangements with the six Medical Oncologists for Fiscal Years 2005 through 2008 comply with the *Bona Fide* Employment Exception. Halifax is also entitled to judgment as a matter of law as to the Stark Law compliance of the terms of any other Medical Oncology agreements in the years prior or subsequent.

1. The Medical Oncology Contracts Are Direct Compensation Arrangements

There is no material dispute of fact the Medical Oncologists are employees of Halifax. The analysis and conclusions in Section V(A)(1) above with respect to the Neurosurgeons apply equally to the Medical Oncologists. Accordingly, Halifax is entitled to judgment as a matter of law the agreements with the Medical Oncologists are direct compensation arrangements.

2. It Is Undisputed The Medical Oncologists' Contracts Are Fair Market Value And Commercially Reasonable

Halifax's expert provided uncontroverted testimony that the Medical Oncologists' compensation was FMV and commercially reasonable. Ex. 16, O'Brien Rep., at 11, 22; Ex. 69, Peburn Dep., at 110:15-113:5. The United States' expert excluded the Medical Oncologists entirely from the scope of her final report even though the statement of work in her initial expert report included an FMV and commercial reasonableness analysis of their contracts. Ex. 49, McNamara Rep. (Aug. 31, 2012); Ex. 78, McNamara Dep., at 93:3-13, 99:2-12. The United

States cannot deny, however, that Ms. McNamara agreed Exhibit D of her initial report included “many instances where the physician compensation was below what [she] calculated to be the MGMA median cash compensation.” Ex. 79, McNamara Dep., at 97:6-13. As such, the evidence indisputably shows the compensation paid to the Medical Oncologists met the FMV and commercial reasonableness criteria of the *Bona Fide* Employment Exception.

3. As A Matter Of Law, The Medical Oncologists’ Compensation Includes A Permissible Productivity Bonus Because The Payment Of The Bonus Was Based On Each Medical Oncologist’s Personally Performed Services

The United States premises its entire case against the Medical Oncologists’ agreements on a flawed argument that the bonuses paid out of a pool funded by the Medical Oncology Department’s operating margin in Fiscal Years 2005 through 2008 impermissibly took into account the volume or value of referrals. This count fails as a matter of law because the *Bona Fide* Employment Exception makes clear the prohibition on compensation taking into account the volume or value of referrals does not apply to productivity bonuses based on a physician’s personally performed services. Indeed, CMS revised the definition of “referral” to affirmatively exclude personally performed services from the definition. 66 Fed. Reg. at 871.

The Medical Oncologists’ bonuses were calculated on the basis of each physician’s own personal productivity. Ex. 80, Cason Dep., at 108:22-110:9; Ex. 81, Peburn Dep., at 199:4-200:2; Ex. 82, Garthwaite Dep., at 228:2-10. The text of the statutory exception is unambiguous, and states as follows:

(2) Any amount paid by an employer to a physician [. . .] who has a *bona fide* employment relationship with the employer for the provision of services if—
[. . .]

(B) the amount of the remuneration under the employment—

- (i) is consistent with the fair market value of the services, and
- (ii) is not determined in any manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician [...]

Subparagraph (B)(ii) shall not prohibit the payment of remuneration in the form

of a productivity bonus based on services performed personally by the physician (or an immediate family member of such physician).

42 U.S.C. § 1395nn(e)(2) (emphasis added); *see also* 42 C.F.R. § 411.357(c).

The prohibition on compensation that *directly* or *indirectly* takes into account the volume or value of referrals generated by the physician in subparagraph (B)(ii) is limited by the phrase at the end of the statutory provision, which protects all productivity bonuses that are allocated based on personally performed services. The productivity bonus qualification limits, and is not in addition to, subparagraph (B)(ii). In fact, the productivity bonus provision nullifies the volume or value of referral prohibition in (B)(ii) when the bonus is allocated based on personally performed services. 42 U.S.C. § 1395nn(e)(2). Ex. 83, Barsky Dep., at 151:2-9 (“So generally, if a physician is personally performing services, essentially, if they're referring to themselves for services with services that they perform personally, it's not even considered a referral for purposes of the Stark law, you don't even need to determine whether you fit within an exception, because you haven't even violated the law.”).

Through regulations, CMS removed personally performed services from the definition of “referral.” 42 C.F.R. § 411.351; Ex. 83, Barsky Dep., at 151:2-9. Logically, there is no benefit from the productivity bonus provision if only personally performed services can apply because those services do not need the safe harbor provided by the provision since they are not even referrals. The statute is not clear what services are protected by the productivity bonus provision if not personally performed services. As such, so long as the bonus is allocated based upon the physician’s personally performed services, it complies with the productivity bonus provision.

Here, there is no dispute Halifax allocated and distributed the bonus pool based solely on each Medical Oncologist’s personal productivity. Ex. 108, Peburn Dep., at 198:19-199:3. The Medical Oncology bonuses allow the physician’s compensation to vary based upon how hard she

works, *not* based on referrals of DHS. 42 U.S.C. § 1395nn(e)(2).

The United States argues the bonus payments *indirectly* took into account the volume or value of referrals. The evidence of the purported indirect connection is irrelevant because the productivity bonus provision nullifies the volume or value of referrals provision in the *Bona Fide* Employment Exception. Further, the evidence of this purported indirect connection is tenuous at best. The department's operating margin, of which only 15% was included in the bonus pool, is influenced by a host of financial metrics that bear no relation to the volume or value of referrals, such as the salary costs of ancillary support staff. The *Bona Fide* Employment Exception does not require compensation to be set in advance, and, in any case, expressly permits percentage compensation if the *methodology* is set in advance and does not change over the course of the arrangement. 69 Fed. Reg. at 16,066. Of course, individual physicians could not be paid a percentage of the revenues generated by their referrals, but that is not what is happening here. The percentage of the operating margin, which bears at most an attenuated relationship to referrals, simply determines the size of the pool, and not the amount of any individual physician's distribution, which is based on the physician's personal productivity.

Halifax did not calculate the bonus pool to maximize the inclusion of DHS. Halifax calculated the operating margin to include outpatient prescription drugs and facility fees associated with outpatient office visits, but excluded revenue from laboratory services, radiology services, and inpatient services. Ex. 84, Foster Dep., at 69:2-71:3; Ex. 85, Garthwaite Dep., at 66:13-67:24. As shown by Exhibit 86, each Medical Oncologist's annual compensation bore no correlation to the volume or value of his or her referrals, but rather to their personal productivity. Ex. 86, Medical Oncology Compensation Graph.

C. The Compensation Arrangement With Dr. Molpus Satisfies The *Bona Fide* Employment Exception.

Dr. Molpus is erroneously identified by the United States as a Medical Oncologist, and is actually a gynecological oncologist compensated under an entirely different compensation arrangement. Dr. Molpus' compensation arrangement complied with the *Bona Fide* Employment Exception in all respects. The United States' FMV/commercial reasonableness expert did not include any analysis or conclusions about his compensation in her final report. Ex. 49, McNamara Rep. More importantly, there is no dispute of fact Dr. Molpus was never paid an incentive bonus of the kind paid to the Medical Oncologists. *See* Dr. Molpus Decl. Ex. 87,; Ex. 88, Garthwaite Dep., at 40:2-41:15, 105:23-106:4. Dr. Molpus was eligible for incentive bonus, but these bonuses were never paid. Ex. 89, Garthwaite Dep., at 125:6-17; Ex. 87, Molpus Decl. Ex. 89, Garthwaite Dep., at 125:18-25; Ex. 87, Molpus Decl. Accordingly, Halifax is entitled to judgment as to any claims associated with Dr. Molpus.

D. The Compensation Arrangements With The Physicians Also Satisfy The Indirect Compensation Arrangement Exception

Even if this Court determines that Halifax has an indirect compensation arrangement with the physicians listed in the Complaint, Halifax is entitled to judgment as a matter of law that the arrangements with the Neurosurgeons and Medical Oncologists satisfy the indirect compensation arrangement exception and that the United States has not identified any prohibited referrals to Halifax Staffing by the Physicians. 42 C.F.R. § 411.357(p).

This exception protects an indirect compensation arrangement between a physician and the entity furnishing DHS if the following are met: (1) the physician's compensation is FMV and not determined in any manner that takes into account the volume or value of referrals or other business generated by the referring physician for the DHS entity; (2) for *bona fide* employment relationships, the contract is for identifiable services and is commercially reasonable even if no

referrals are *made to Halifax Staffing*; and (3) the compensation arrangement does not violate the Anti-Kickback Statute (“AKS”). *Id.* (emphasis added). The exception has no requirement that the compensation to the physician be set in advance. CMS’ position is that “all physicians, whether employees, independent contractors, or academic medical center physicians, can be paid productivity bonuses based on work they personally perform.” 69 Fed. Reg. at 16,067.

1. All Of The Physician Arrangements Were Commercially Reasonable In The Absence Of Referrals To Halifax Staffing

If the Physicians’ agreements were indirect with Halifax Staffing as the employer, they were commercially reasonable for the reasons set forth in Sections V(A)(2)(b) and V(B)(2)(c), and because there were no referrals to Halifax Staffing that could have unduly influenced the terms in the agreements. 42 C.F.R. § 411.357(p)(2); Ex. 49, McNamara Rep., at 31.

2. None Of The Physician Agreements Violated The Anti-Kickback Statute, Nor Does the United States Allege They Did

There is no material dispute of fact that there is no evidence any of the Physicians’ agreements violated the AKS, and the United States does not allege that they do.

3. The Compensation Arrangements With The Neurosurgeons Satisfy All Criteria In The Indirect Compensation Arrangement Exception

As stated in Section V(A)(2)(a) of this motion, Halifax’s Neurosurgeons’ agreements are based on FMV. Ex. 90, Peburn Decl.; Ex. 91, Peburn Dep., at 102:14-103:17. Further, their compensation was not determined in any manner that takes into account the volume or value of referrals or other business generated because the compensation was based solely on personally performed services. CMS has made clear productivity bonuses based on personally performed services are permissible for all physicians. 69 Fed. Reg. at 16,067 (“The result of these interpretations is that all physicians, whether employees, independent contractors, or academic medical center physicians, can be paid productivity bonuses based on work they personally

perform.”). CMS has determined “other business generated” excludes personally performed services. 42 C.F.R. § 411.354(d)(3). Halifax is entitled to judgment as a matter of law the Neurosurgeons’ agreements satisfy the indirect compensation arrangement exception.

4. The Medical Oncologists’ Arrangements Do Not Take Into Account The Volume Or Value Of Referrals Or Other Business Generated

The United States has not offered any expert evidence that the Medical Oncologists’ agreements were not FMV. Nor was the Medical Oncologists’ compensation determined in a manner that took into account the volume or value of referrals or other business generated because it was derived from a fixed salary and productivity bonuses. The bonuses paid for Fiscal Years 2005 through 2008 were distributed exclusively on the basis of each individual Medical Oncologist’s personally performed services. CMS expressly excluded personally performed services from the definition of referral so that a “productivity bonus based on personally performed work would not be based on the volume or value of referrals.” 69 Fed. Reg. at 16,067. There is no question, as a matter of law, that physicians may receive personal productivity bonuses. Moreover, the undisputed facts make clear the Medical Oncologists’ compensation did not, in practice, vary with the volume or value of referrals to Halifax. *See* Ex. 86. For the foregoing reasons, Halifax is entitled to judgment as a matter of law that the Medical Oncology agreements satisfy the indirect compensation arrangement exception.

E. **The United States Erroneously Includes Claims That Are Not Implicated By The Stark Law**

Thousands of claims included by the United States cannot, as a matter of law, reflect referrals covered by the Stark Law’s Billing Prohibition. The United States bears the burden of establishing a referral was made to an entity, *i.e.*, Halifax violated the Billing Prohibition by submitting claims for services resulting from prohibited referrals. *United States ex rel. Kosenske v. Carlisle HMA, Inc.*, 554 F.3d 88, 95 (3d Cir. 2009) (“Once the plaintiff or the government has

established proof of each element of a violation under the [Stark] Act, the burden shifts to the defendant to establish that the conduct was protected by an exception.”). The United States’ purported claims expert, Ian Dew, analyzed hospital inpatient and outpatient claims, which reflect the facility or technical fee component of services rendered to Medicare beneficiaries, and non-institutional outpatient claims, which reflect the professional fees for services rendered to Medicare beneficiaries (“Carrier Claims”). Mr. Dew’s analysis blindly relies on information reflected on Halifax Medicare claim forms as proof of purported referrals and, therefore includes thousands of claims that cannot under any circumstances be evidence of prohibited referrals.

1. Evaluation And Management Services Are Not DHS

The Stark Law prohibits the submission of claims for DHS. 42 U.S.C. § 1395nn(a)(1)(B). The regulations contain an exhaustive list of items and services that are DHS. E&M services are not on that list. 42 C.F.R. § 411.351; *see also* Moran Rep., at 15. The United States’ 30(b)(6) witness agreed E&M services are not DHS. Ex. 92, Stone Dep., at 37:4-6. Nonetheless, Mr. Dew included Carrier Claims where the only services reported are professional E&M services. These are not claims *for DHS* and must be dismissed as not subject to the Billing Prohibition.

2. Physicians’ Professional Services At Issue Are Not DHS

As discussed in Section V(A), personally performed services are, by definition, not “referrals,” even when for DHS. 42 C.F.R. § 411.351; 66 Fed. Reg. at 871; Ex. 93, Barsky Dep., at 150:16-152:16. Accordingly, a claim for personally performed services does not violate the Billing Prohibition because there has been no “referral” for Stark Law purposes – even if the treating physician has a prohibited financial relationship with the entity.

It is undisputed that when a physician is listed in the “Rendering Provider” field on a Carrier Claim, it is a professional physician service, which are not DHS. Ex. 94, 30(b)(6) Sandlin Dep., at 180:1-3; Ex. 95, Moran Rep., at 16. Even if they are DHS, personally performed

services are not DHS. Despite this undisputed fact, Mr. Dew included Carrier Claims where at least one of the Physicians was a “Rendering Provider.” These claims forms do not, therefore, identify prohibited “referrals” by the Physician. Halifax is entitled to judgment as a matter of law on all of these Carrier Claims where a Physician is identified as the Rendering Provider.

3. Claims For Services Performed On Patients Who Self-Referred To Halifax Are Not Subject To The Stark Law Billing Prohibition.

The Stark Law Referral Prohibition does not prohibit claims for payment where there has been no “referral.” The Referral Prohibition prohibits referrals “to the entity” if the physician has a financial relationship with that entity. 42 U.S.C. § 1395nn(a)(1)(A). The Billing Prohibition, in turn, prohibits the submission of claims for services furnished in violation of the Referral Prohibition. 42 U.S.C. § 1395nn(a)(1)(B). CMS has stated, “[T]he relevant inquiry is whether the physician has made a referral, directly or indirectly, to the entity furnishing DHS, in other words, whether he or she is referring ‘to’ that entity.” 66 Fed. Reg. at 873.

Many Halifax claims reflect services furnished to patients that were either self-referred to Halifax’s Emergency Department or were transferred from an unrelated provider. Ex. 95, Moran Rep., at 13-14; Ex. 96, Sandlin Dep., at 86:14-87:10; Ex. 97, Rooke Dep., at 45:16-47:12. Common sense dictates that a patient who self-referred or was transferred to Halifax from another provider was not referred to Halifax by one of the Physicians. In such instances, the physician cannot be said to have referred a patient *to Halifax*, even if he or she ordered, requested, certified or recertified the need for an item or service, or established a plan of care. The United States’ disregard of this flaw in its reliance on the Medicare claim forms is further evidence that the forms are not credible evidence of prohibited referrals.

4. Claims For Services Furnished By Entities Other Than Halifax Should Be Excluded

Halifax’s expert identified 3,174 claims in the United States’ claims summary that were

not submitted for payment by Halifax. Ex. 95, Moran Rep., at 16. These claims were submitted by a variety of different entities, including East Central Florida Outpatient Imaging, LLC (“ECFOI”), none of which are named by the United States in its Complaint. The United States has offered no evidence, and Halifax has expressly denied, that it bills and collects for services provided by ECFOI. *See* Ex. 98, Objections and Responses to United States’ Eighth Set of Reqs. for Production and Sixth Set of Req. for Admis. (Apr. 10, 2013); Ex. 99, Rahn Dep. at 69:9-14. In addition to not naming other legal entities in its Complaint, the United States offered no evidence to establish the existence of a financial relationship between the Physicians and these non-Halifax legal entities. If there is no financial relationship, the Stark Law does not apply. Halifax is therefore entitled to judgment as a matter of law as to these claims.

5. Designation Of The “Attending Physician” Or “Operating Physician” On CMS Form 1450 Does Not Provide Sufficient Evidence Of A Referring Physician

As set forth above, the United States’ sole reliance on Halifax’s Medicare claims forms results in the incorrect and inappropriate inclusion of thousands of claims for which it could never be entitled to relief. Reliance on Medicare claims forms alone should not be sufficient to establish that a prohibited referral was made. The United States could have relied upon Halifax’s patient records obtained during the course of discovery but did not. To shortcut its burden of proof of referrals, the United States erroneously relies on the designation of a Physician as the “attending physician” or the “operating physician” on a Halifax claim form.

During the relevant time period, claims for hospital services have been submitted using two versions of the same claim form (the CMS Form 1450): the UB-92 and the UB-04. CMS provides instructions to hospitals regarding which physicians should be listed as attending physician and operating physician. Ex. 100, CTRS. MEDICARE & MEDICAID SERVS., MEDICARE INTERMEDIARY MANUAL, § 3604 (2001) (instructing hospitals to list in the “attending/referring

physician” field on the UB-92 the physician “primarily responsible for the care of the patient from the beginning of the hospital episode.”); Ex. 101, CTRS. MEDICARE & MEDICAID SERVS., MEDICARE CLAIMS PROCESSING MANUAL, ch. 25, § 75.5 (2013) (instructing hospitals to list in the “attending provider” field of the UB-04 the individual with “overall responsibility for the patient’s medical care and treatment” and in the “operating provider” field the individual with “primary responsibility for performing the surgical procedure(s)”). CMS’ instructions regarding identification of the attending or operating physician bear no relation to the Stark Law definition of “referring physician,” which is the physician who orders, requests, or certifies or recertifies the need for, an item or service, or establishes a plan of care. 42 U.S.C. § 1395nn(h)(5). Indeed, CMS’ instructions do not suggest that hospitals could possibly be on notice that by listing a physician in the attending or operating physician field they are designating such a physician as a “referring physician” for purposes of the Stark Law (*e.g.*, a reference to 42 U.S.C. § 1395l(q)).

The disconnect between the claims forms and the concept of a Stark Law referral is unsurprising as the claims forms are designed for hospital billing and claims processing purposes, not to identify referrals or referring physicians. The United States’ attempt to leverage these forms as proof of Stark Law referrals is a failed attempt to fit a square peg into a round hole.

The Court should disregard the finding of the Northern District of Illinois in *United States v. Rogan*, 459 F.Supp.2d 692 (N.D. Ill. 2006), *aff’d*, 517 F.3d 449 (7th Cir. 2008) that the attending provider must be the referring physician for Stark Law purposes. The *Rogan* court considered this question *sua sponte* and without reviewing any arguments submitted by either party. Unlike this Court, the *Rogan* court did not have the benefit of expert or 30(b)(6) testimony from CMS officials on these very questions. In reaching its conclusion, the *Rogan* court mistakenly focused on the requirement to designate a referring physician in 42 U.S.C. §

13951(q)(1) and a misguided citation to the *Home Health Agency Manual*, which, as the name suggests, has nothing to do with hospital services.

42 U.S.C. § 13951(q) requires hospitals to list the name and unique personal identification number of a referring physician, if “the [hospital] knows or has reason to believe there has been a referral by a referring physician.” By its express terms, the requirement is only applicable for hospital outpatient claims, not inpatient claims. Ex. 107, United States’ Responses and Objections to Halifax’s Third Set of Reqs. for Admis. no. 38 (Dec. 10, 2012). This statute is only applicable where the hospital has knowledge there has been a referral. Thus, section 13951(q) does not apply to inpatient claims and claims where the hospital has no knowledge of a referral. *See accord* Ex. 102, Sandlin Dep., at 85:2-12. In contrast, CMS requires a hospital to list an attending physician on *every* claim, and an operating physician where there is one. The *Rogan* court’s reliance on section 13951(q) to establish a nexus between an attending/operating physician on a claim form has superficial appeal but no regulatory support – one simply does not flow from the other. A physician listed as attending or operating physician on a claim form *may* be, but is not necessarily, a Stark Law referring physician. Ex. 103, Sandlin Dep., at 84:21-85:5. In fact, there may be no referring physician at all. *Id.* This is further reason why the patient medical record should be the basis for identifying Stark Law referrals.

VI. LEGAL ARGUMENT ON FALSE CLAIMS ACT CAUSES OF ACTION

A. The United States’ FCA Causes Of Action One Through Three

The United States’ Causes of Action under Section 3729(a), subsections (1)(A)-(B), (1)(G), and (a)(7), are dependent on a finding Halifax violated the Stark Law. The FCA elements are set forth in Section V(B) and incorporated here. Of particular importance are the falsity and knowledge elements for which the United States bears the burden of proof. Imprecise statements or differences in interpretation growing out of a disputed legal question, by law, are not false

under the FCA.

B. Halifax Did Not Knowingly Submit, Present Or Use False Statements To Obtain Payment For False Claims

The United States cannot maintain its FCA Causes of Action regardless of whether this Court finds that a Stark Law violation occurred. So long as Halifax had a reasonable basis for believing that the terms of the contracts at issue met the criteria for the applicable Stark Law exception and were commercially reasonable and for FMV, Plaintiffs cannot prove by the necessary preponderance of the evidence that Halifax's Medicare claims for payment were false or that Halifax "knowingly" submitted or presented false claims or used false statements to get payment of false claims. *See Brooks v. United States*, 64 F.3d 251, 255 (7th Cir. 1995) (noting that the Government bears the burden of proving the violation by a preponderance of the evidence); *see also United States ex rel. Watson v. Connecticut Gen. Life Ins. Co.*, Civ. No. 98-6698, 2003 U.S. Dist. LEXIS 2054, at *16 (E.D. Pa. Feb. 11, 2003). This scienter requirement is "critical to the operation of the False Claims Act," and, ultimately, to the resolution of this case. *United States ex rel. Hochman v. Nackman*, 145 F.3d 1069, 1073 (9th Cir. 1998).

As set forth in the authorities identified in Section IV(B), the United States cannot establish knowing conduct through imprecise statements or difference in interpretation growing out of a disputed legal question, by law, are not false under the FCA. The "reckless disregard" standard for FCA liability has been held to require at least a showing of an aggravated form of gross negligence, or, "gross negligence-plus." *United States v. Krizek*, 111 F.3d 934, 941-42 (D.C. Cir. 1997). Numerous courts have held that mere noncompliance with a statute, regulation or contractual provision, without more, cannot constitute a "knowing" FCA violation. *See United States v. Southland Mgmt. Corp.*, 326 F.3d 669, 681 (5th Cir. 2003) (Jones, J., Concurring); *see also* *cites supra*, Section IV(B).

1. The Neurosurgeons' Agreements

The United States cannot show the requisite scienter to maintain its FCA claims regarding the Neurosurgeons without evidence Halifax knew the agreements did not comply with the Stark Law. The United States does not allege any provision in the Neurosurgeon agreements violated the Stark Law, and the bonuses fit squarely within the requirements of the *Bona Fide* Employment Exception.

2. The Medical Oncologists' Agreements

Halifax always believed that the Fiscal Years 2005-2008 Medical Oncology incentive bonuses fit within the *Bona Fide* Employment Exception as well. The Stark Law is vague on the meaning of the “volume or value of referrals,” and its interpretation of the productivity bonus provision ignores the fact that the provision nullifies the volume or value of referrals prohibition. While the parties have two different interpretations of the Stark Law’s treatment of the phrase “take into account the volume or value of referrals,” the United States cannot cite to any evidence Halifax did not act in good faith in the process of negotiating and approving the incentive bonus for Fiscal Years 2005, 2006, and 2007. To the contrary, Halifax incorporated a legal Stark Law review into the drafting of every Physician’s agreement. *E.g.*, Ex. 104, Peburn Dep., at 130:1-9, 156:16-24, 170:5-17; Ex. 47, Contract Management Review Policy.

Halifax relied in good faith on the advice of counsel from the General Counsel at the inception of the incentive bonus for 2005, 2006, and 2007 and, later, in 2008 upon competent outside counsel after Relator raised a concern about the issue. Halifax’s conduct both at the inception of the incentive bonus for 2005 through 2007 and during 2008 meets the requirements for establishing good faith reliance on the advice of counsel. The assertion of good faith reliance on the advice of counsel has applicability in both civil and criminal cases. *SEC v. Mut. Benefits Corp.*, 2004 U.S. Dist. LEXIS 23008, at *71-72 (S.D. Fla. Nov. 10, 2004) (stating that “[g]ood

faith reliance on the advice of counsel may negate, or mitigate against a finding of, scienter”). In a civil FCA case, the request for and receipt of the advice of counsel can be relevant to whether the defendant acted knowingly. *See United States v. Newport News Shipbuilding, Inc.*, 276 F. Supp. 2d 539, 565-66 (E.D. Va. 2003) (explaining that evidence of the advice of counsel may “contradict any suggestion that a [defendant] ‘knowingly’ submitted a false claim”). In the Eleventh Circuit, the assertion of the advice of counsel requires proof of two elements: (1) full disclosure of all relevant facts to counsel and (2) good faith reliance on the advice of counsel. *See United States v. Condon*, 132 F.3d 653, 656 (11th Cir. 1998); *Boca Raton Cmty. Hosp., Inc. v. Tenet Healthcare Corp.*, 502 F. Supp. 2d 1237, 1255 (S.D. Fla. 2007) (laying out same standard in context of civil RICO action) “The issue of good faith reliance is . . . a fact question.” *Mee Indus. v. Dow Chem. Co.*, 608 F.3d 1202, 1219 (11th Cir. 2010). Full disclosure of all relevant facts requires that a “full, correct, and fair statement of all material facts” be provided to the counsel from whom the advice is requested. *See Mee Indus. v. Dow Chem. Co.*, No. 6:05-cv-1520-Orl-310AB, 2008 U.S. Dist. LEXIS 116722, at *14-15 (M.D. Fla. Oct. 31, 2008); *see also United States v. Eisenstein*, 731 F.2d 1540, 1543 (11th Cir. 1984) (stating the defendant must first make “a full disclosure of all facts that are relevant to the advice for which he consulted the attorney”); *United States v. Pasquariello*, No. 89-6196-Cr-Ungaro-Benages, 1994 U.S. Dist. LEXIS 20924, at *50 (S.D. Fla. Apr. 19, 1994) (stating “[a]nother element of the advice of counsel . . . defense is that the Defendant [make] a full and accurate report of all material facts of which he had the means of knowledge to his expert”).

Halifax meets the test of good faith reliance on advice of counsel because it did not adopt the incentive bonus for Fiscal Year 2005 until after the General Counsel reviewed and approved the agreements. His review and approval is established by his initialing of the contract review

cover sheets for each agreement. Ex. 13, Contract Review Cover Sheet.

Years later, in October 2008, when Relator first raised a concern about the incentive bonus, the Associate General Counsel immediately began, at the General Counsel's direction, an analysis of the complex legal issue, resulting in a series of preliminary research memoranda. *See, e.g.*, Ex. 105, Davidson Decl. at E, A. Pike Mem., Nov. 10, 2008. In order to obtain the benefit of an independent legal analysis, the General Counsel solicited a legal memorandum from competent outside counsel analyzing the relevant Stark Law issue, assigned Associate General Counsel Pike to oversee the progress of the outside counsel review, and ultimately received and relied upon the outside counsel memorandum prior to authorizing Halifax's accounting department to pay the Fiscal Year 2008 bonus. *Id.* at F, D. Davidson email to I. Coleman, Nov. 10, 2008; Ex. 106, A. Pike Fax, Nov. 20, 2008, to D. Melvin With Medical Oncology Agreement Attach.; Ex. 105 at G, McDermott Will & Emery Mem. Feb 09, 2009; *Id.* at I, D. Davidson Email to T. Garthwaite, Mar. 06, 2009; Ex.109, A. Pike email to A. Foster, Mar. 4, 2009.

Ms. Pike's memoranda regarding her preliminary conclusion that the Medical Oncology agreements violated the Stark Law is not evidence that Halifax acted "knowingly" under the FCA. Any reliance by the United States on these documents is contradicted by Ms. Pike's deposition testimony. Ms. Pike testified unequivocally that Halifax acted responsibly in investigating the concerns raised by Relator and by her preliminary analysis. *E.g.*, Ex. 110, Pike Dep. (May 20, 2013), at 7-11, 14-20. More importantly, Ms. Pike testified that at the time she authored the memoranda she had very little experience conducting stark analyses and that the memoranda "[did not] go through what a real Stark analysis goes through" and, therefore, indicated that she was "not fully appreciating the complexities of Stark" at the time she prepared them. *Id.* at 35, 153, 157-61 (rough transcript). Ms. Pike also testified that given her current

experience, she now recognizes that the Stark statute is “an incredibly complicated law” and that her first-time analysis in her memorandum “was not correct.” *Id.* at 35.

The General Counsel and Associate General Counsel communicated with absolute candor to outside counsel about the terms of the Medical Oncologists’ bonus and waited until receiving the completed advice of outside counsel before authorizing payment of the 2008 bonus. There is no evidence Halifax compromised the integrity of the outside counsel legal advice which concluded that, by paying an incentive bonus based on each Medical Oncologist’s personally performed services, the agreement complied with the *Bona Fide* Employment Exception.

C. The Halifax Claims Are Not False

The United States has no evidence to counter Halifax’s evidence regarding its good faith interpretation of the *Bona Fide* Employment Exception. Given the wide latitude CMS gives to providers to establish FMV and commercial reasonableness methodologies, the United States’ stunning lack of expert testimony or reasoning contradicting Halifax’s evidence leads to the inexorable conclusion Halifax’s claims cannot be false for purposes of FMV or commercial reasonableness. In addition, the United States’ 30(b)(6) witness testified that CMS does not provide specific guidance about how to apply the relevant FMV and commercial reasonableness tests. Exs. 34, 64, Barsky Dep., at 40:1-17, 65:17-66:16. Halifax indisputably had a good faith basis for believing the contracts were based on FMV, were commercially reasonable, and did not impermissibly take into account the volume or value of referrals. Plaintiffs’ FCA claims therefore must fail. *See United States ex rel. Williams v. Renal Care Group*, 696 F.3d 518, 532 (6th Cir. 2012) (“The False Claims Act is not a vehicle to police technical compliance with complex federal regulations.”).

D. Failure To Identify Prohibited Referrals Or Any FCA Damages

As set forth in Section VI(E), the United States has failed to identify any referrals

prohibited by the Stark Law. The gargantuan scope of the damages demanded by the United States – treble damages for years of Medicare reimbursement for any claims for hospital services provided to any patient that one of the Physicians saw – demands that the United States prove that the Physicians made prohibited referrals for DHS. The United States has been on notice from Halifax for nearly a year during discovery that Halifax would demand proof of prohibited referrals that tainted Medicare claims that resulted in damages suffered by the United States.

VII. LEGAL ARGUMENT ON COMMON LAW CAUSES OF ACTION

Due to the lack of evidence supporting the DOJ's Stark Law and FCA claims, the DOJ's common law Causes of Action Four (Unjust Enrichment), Five (Payment By Mistake), and Six (Equitable Remedies of Disgorgement, Constructive Trust, and Accounting) must also be dismissed. The Eleventh Circuit has explicitly provided that where summary judgment is entered dismissing the federal claims, the district court may dismiss the remaining state and common law claims. *Nolin v. Isbell*, 207 F.3d 1253 (11th Cir. 2000); *Republic of Panama v. BCCI Holdings (Luxembourg) S.A.*, 119 F.3d 935, 951 n. 26 (11th Cir. 1997) ("After dismissing Panama's federal claims against the . . . defendants, the district court correctly dismissed its remaining state law claims against these defendants"); *see also Benjamin v. Holy Cross Hospital, Inc.*, No. 11-62142-CIV, 2013 WL 1334565, at *13-14 (S.D. Fla. Mar. 29, 2013) ("Because summary judgment will be entered . . . on all federal claims, the remaining potential state and common law claims will be dismissed"). Dismissing the United States' common law claims is also supported by 28 U.S.C. § 1367(c)(3), which provides that "[t]he district courts may decline to exercise supplemental jurisdiction over a claim under subsection (a) if . . . the district court has dismissed all claims over which it has original jurisdiction."

To the extent the United States asserts independent liability for Causes of Action Four and Five, Halifax asserts its fact evidence in the defense of Causes of Action One through Three.

Halifax has provided all of the health care services set forth in its claims for Medicare payment.

Likewise, the United States has not mistakenly paid for any items or services that Halifax provided to it. Absent an equitable basis, the United States is not entitled to equitable relief.

VIII. CONCLUSION

For the reasons stated herein, Halifax is entitled to judgment as a matter of law on the subject Stark Law and FCA claims.

Dated: May 28, 2013

Respectfully submitted,

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Counsel to Defendants Halifax Hospital Medical Center and Halifax Staffing, Inc.

UNITED STATES OF AMERICA <i>ex rel.</i> , and)	)	
ELIN BAKLID-KUNZ, Relator	)	
	)	
Plaintiffs	)	
	)	
v.	)	CASE NO.: 6:09-CV-1002-ORL-31TBS
	)	
HALIFAX HOSPITAL MEDICAL CENTER)	)	JUDGE GREGORY A. PRESNELL
d/b/a HALIFAX HEALTH a/k/a HALIFAX)	)	[FALSE CLAIMS ACT – QUI TAM]
COMMUNITY HEALTH SYSTEM a/k/a)	)	
HALIFAX MEDICAL CENTER and)	)	DISPOSITIVE MOTION
HALIFAX STAFFING, INC.	)	
	)	
Defendants	)	
	)	

PROPOSED ORDER

This matter is before the Court on Defendant’s Motion for Summary Judgment. For the reasons that follow, the Motion for Summary Judgment is granted as to the following findings of fact and conclusions of law.

1. A provider may use any reasonable methodology to determine whether a proposed employed physician arrangement is based on Fair Market Value (“FMV”).
2. If the provider used a reasonable FMV methodology and implemented that methodology in good faith, the employed physician arrangement is based on FMV.
3. The United States may only challenge the FMV aspect of an employed physician arrangement by analyzing the reasonableness of the provider’s FMV methodology.
4. The United States cannot substitute its own expert’s differing FMV methodology in order to support the analytical result that it seeks.
5. The Neurosurgeons’ compensation arrangements were negotiated and implemented based on a reasonable FMV methodology.

6. There is no genuine dispute of material fact that the compensation arrangements with the Neurosurgeons were based on FMV.

7. There is no dispute of material fact that the Medical Oncologists' compensation arrangements were negotiated and implemented based on a reasonable FMV methodology.

8. There is no genuine dispute of material fact that all of the Halifax compensation arrangements with the Medical Oncologists are based on FMV.

9. The United States has not publicly announced any specific criteria for determining if an arrangement is commercially reasonable under the Stark Law.

10. The compensation arrangements with the Neurosurgeons were commercially reasonable.

11. Halifax's compensation arrangements with the Medical Oncologists were commercially reasonable.

12. The Medical Oncologists' incentive bonus for Fiscal Years 2005 through 2008 was allocated based on each physician's personally performed services, and, therefore, met the productivity bonus provision of the *Bona Fide* Employment Exception.

13. If the Neurosurgeons' compensation arrangements did not violate the Stark Law, Halifax cannot be liable under the FCA.

14. If the Medical Oncologists' compensation arrangements did not violate the Stark Law, Halifax cannot be liable under the FCA.

15. Dr. Kelly Molpus, employed Halifax oncological surgeon, was not paid any incentive bonuses of the kind identified in the Complaint. Therefore, his agreement does not raise any of the factual or legal issues in the Complaint.

16. Halifax acted in good faith in the negotiation of the Medical Oncologists'

compensation arrangements as shown by the competent legal advice applied by Halifax's General Counsel at the time the Medical Oncologists' agreements were negotiated and approved for Fiscal Year 2005 and, therefore, could not have violated the FCA for any incentive bonuses paid for Fiscal Years 2005, 2006 or 2007.

17. Halifax acted in good faith in the negotiation of the Medical Oncologists' compensation arrangements as shown by its reliance on the competent outside counsel legal advice applied by its General Counsel during Fiscal Year 2008 after concerns were first raised by Relator about the arrangements' compliance with the Stark Law.

18. The United States may not prove that prohibited referrals were made under the Stark Law by relying solely on the information identified on the provider's Medicare claims for payment and that the patient medical record is the best evidence for establishing whether a provider order, certified or re-certified a prohibited Designated Health Services for purposes of Stark Law liability or damages.

19. Medicare and Medicaid claims for Evaluation and Management (E&M) Services are not claims for DHS, patient self-referrals, patient transfers from other providers to Halifax, and claims for personally performed services are not prohibited referrals under the Stark Law.

20. Halifax did not submit false claims to any Medicaid program.

21. The United States has not taken any discovery of the clinical medical necessity of the coding levels used by any of the Neurosurgeons for determining the complexity of each patient case.

22. The Neurosurgeons were compensated at FMV based on the wRVU-to-compensation metric.

23. The United States has not provided any evidence that it has analyzed the work

Relative Value Units for either the Medical Oncologists or the Neurosurgeons to support its FMV expert's assertion that the work RVUs are unreliable or invalid for purposes of determining any individual Physician's compensation.

24. The United States has not established that it is entitled to relief under any of the common law Causes of Action (Four, Five or Six) in its Complaint.

For the reasons that follow, the Motion for Summary Judgment is granted as to:

1. Cause of Action I, allegations of presentation of false claims in violation of the FCA, 31 U.S.C. § 3729(a)(1) and (a)(1)(A);
2. Cause of Action II, allegations of using false statements to get false claims paid in violation of the FCA under 31 U.S.C. § 3729(a)(1)(B);
3. Cause of Action III, allegations that Halifax made a false record material to an obligation to pay in violation of the FCA under 31 U.S.C. § 3729(a)(7) and (a)(1)(G);
4. Cause of Action IV, allegations of unjust enrichment;
5. Cause of Action V, allegations of payment by mistake; and
6. Cause of Action IV, claims of disgorgement of profits, constructive trust, and accounting.

CONCLUSION

In view of the above, Defendants Halifax Hospital Medical Center and Halifax Staffing's Motion for Summary Judgment (Doc. No. __) is GRANTED.

GREGORY A. PRESNELL
UNITED STATES DISTRICT JUDGE

**IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION**

UNITED STATES OF AMERICA <i>ex rel.</i> , and)		
ELIN BAKLID-KUNZ, Relator)	)	
	)	
Plaintiffs)	)	
	)	
v.)	)	CASE NO.: 6:09-CV-1002-ORL-31TBS
	)	
HALIFAX HOSPITAL MEDICAL CENTER)	)	JUDGE GREGORY A. PRESNELL
d/b/a HALIFAX HEALTH a/k/a HALIFAX)	)	[FALSE CLAIMS ACT – QUI TAM]
COMMUNITY HEALTH SYSTEM a/k/a)	)	
HALIFAX MEDICAL CENTER and)	)	DISPOSITIVE MOTION
HALIFAX STAFFING, INC.)	)	
	)	
Defendants)	)	
	)	

**REQUEST FOR ORAL ARGUMENT IN SUPPORT OF HALIFAX MOTION FOR
SUMMARY JUDGMENT ON THE UNITED STATES COMPLAINT IN
INTERVENTION**

Pursuant to Local Rule 3.01(j) Defendants Halifax Hospital Medical Center and Halifax Staffing, Inc., (“Halifax”) by and through their attorneys, respectfully request that the Court grant oral argument on Halifax’s Motion for Summary Judgment on the United States Complaint in Intervention. Defendants believe that the Court will benefit from oral argument given the complexity of the issues addressed in its Motion for Summary Judgment. Defendants estimate that approximately one hour (30 minutes per side) will be required for oral argument including time reserved for rebuttals.

Dated: May 28, 2013

Respectfully submitted,

s/ David O. Crump

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CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States District Court for the Middle District of Florida using the CM/ECF system on May 28, 2013. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

s/ David O. Crump
David O. Crump

**UNITED STATES DISTRICT COURT FOR THE
MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION**

UNITED STATES OF AMERICA <i>ex rel.</i>	§	
BAKLID-KUNZ,	§	
	§	Civ. Act. No. 6:09-CV-1002-
	§	ORL-31GAP-TBS
	§	
Plaintiffs,	§	
	§	
v.	§	JUDGE Gregory A. Presnell
	§	
HALIFAX HOSP. MED. CTR, et al.	§	
	§	
Defendants.	§	
	§	

**PLAINTIFF UNITED STATES OF AMERICA'S
MOTION FOR PARTIAL SUMMARY JUDGEMENT**

Defendants Halifax Hospital Medical Center and Halifax Staffing, Inc. (collectively, Halifax) knowingly violated the Stark Law and the False Claims Act during a four-year period by entering into employment agreements with six medical oncologists that compensated the physicians based on the operating margin of Halifax’s medical oncology program. In the words of Audrey Pike, Halifax’s then-associate general counsel, “this arrangement is not permitted under the STARK regulations.” HAL-1 0691036-38 (Ex. 28), at HAL-1 0691036 (capitalization in original). Ms. Pike also acknowledged that “the physician may not refer any DHS to the entity during the period of the noncompliant relationship and that the entity may not bill Medicare for DHS referred to it by the physician during that period.” *Id.*, at HAL-1 0691038. This Motion for Partial Summary Judgment will show that the Stark Law applied to Halifax’s contracts with the medical oncologists, that Halifax cannot meet its burden of demonstrating that the contracts met an exception to the Stark Law, and that Halifax acted with knowledge that it was violating the Stark Law when it submitted claims to Medicare. Because Halifax submitted

claims for services in violation of the Stark Law, the United States is entitled to partial summary judgment on Counts One through Five of its Complaint in Intervention (Dkt. No. 73) alleging that Halifax violated various provisions of the False Claims Act and the common law.¹

I. GENERAL LEGAL STANDARD

Summary judgment is appropriate “if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322–23 (1986). “An issue of fact is ‘genuine’ if the record taken as a whole could lead a rational trier of fact to find for the non-moving party.” *Hickson Corp. v. N. Crossarm Co.*, 357 F.3d 1256, 1260 (11th Cir. 2004). A fact is material “if, under the applicable substantive law, it might affect the outcome of the case.” *Id.*, at 1259-60.

The moving party bears the burden of demonstrating that there is no dispute as to any material fact in the case. *See Celotex*, 477 U.S. at 323; *Hickson Corp.*, 357 F.3d at 1260. Once the movant satisfies this burden, the non-moving party must establish “specific facts showing that there is a genuine issue for trial.” *Celotex*, 477 U.S. at 324; *Howard v. BP Oil Co.*, 32 F.3d 520, 524 (11th Cir. 1994). The party opposing summary judgment “must come forward with specific factual evidence, presenting more than mere allegations.” *Gargiulo v. G.M. Sales, Inc.*, 131 F.3d 995, 999 (11th Cir. 1997); *Perkins v. Sch. Bd. of Pinellas County*, 902 F. Supp. 1503, 1505 (M.D. Fla. 1995) (non-movant must designate specific facts showing a genuine issue for trial beyond mere allegations or the party’s perception).

¹The United States is not seeking summary judgment regarding its claims that Halifax violated the Stark Law with respect to its contracts with Drs. William Kuhn, Federico Vinas, and Rohit Khanna.

II. STATEMENT OF UNDISPUTED MATERIAL FACTS

1. Halifax Hospital Medical Center (Halifax Hospital) owns and operates hospitals and medical facilities in Volusia County, Florida, and surrounding counties. Halifax Hospital's primary business is to provide inpatient and outpatient health care services. Compl. (Dkt. No. 73) ¶ 8; Answer (Dkt. No. 112) ¶ 8.

2. Halifax Hospital is a governmental subdivision of the State of Florida and is a special taxing district. Halifax Staffing, Inc. (Halifax Staffing) is an instrumentality of Halifax Hospital and is the vehicle through which Halifax Hospital employs the individuals who work at Halifax Hospital. Answer ¶ 61. Halifax Staffing employs all Halifax Hospital employees. Peburn 30(b)(6) Depo. Tr. (Ex. 1), at 122:7-123:6.

3. Employees are paid through a Halifax Staffing sweep account. Answer ¶ 61. Funds are transferred from the Halifax Hospital Medical Center Special Taxing District master account to the Halifax Staffing sweep account in an amount large enough to only cover checks presented. Halifax's Responses and Objections to United States' Interrogatory No. 3 (Ex. 2).

4. During the fiscal year ending September 2004, wholly owned subsidiaries of Halifax Hospital entered into an agreement with a physician group to provide outpatient imaging services to patients under the name East Coast Florida Outpatient Imaging (ECFOI). The wholly owned Halifax Hospital subsidiaries own 50 percent of ECFOI. Financial Statements, Halifax Hospital Medical Center, (Dec. 10, 2004) (Ex. 3), at HAL-1_0033676-77.

5. In 1965, Congress created the Medicare Program through Title XVII of the Social Security Act. The Medicare Program pays for institutional hospital care, known as Part A, and physician and other ancillary services, known as Part B, for certain individuals who meet the

participate requirements of age, disability, or affliction with end-stage renal disease. 42 U.S.C. §§ 426, 426A, 1395c-1395i-4, 1395K; Compl. ¶¶ 15-16; Answer ¶¶ 15-16.

6. The Centers for Medicare and Medicaid Services (CMS) is the entity within the Department of Health and Human Services responsible for the administration and supervision of the Medicare Program. Compl. ¶ 15; Answer ¶ 15. To assist in the administration of Medicare Part A, CMS contracted with fiscal intermediaries; to assist with the administration of Medicare Part B, CMS contracted with carriers. Compl. ¶¶ 17-18; Answer ¶¶ 17-18. Beginning in November 2006, Medicare Administrative Contractors (MACs) began replacing both fiscal intermediaries and carriers to process and pay both Part A and Part B claims. 71 Fed. Reg. 67960, 68181 (Nov. 24, 2006); 42 C.F.R. 421.5(b); Compl. ¶ 19; Answer ¶ 19.

7. First Coast Service Options, Inc. (First Coast) served as both the fiscal intermediary and carrier for Florida until September 2008, at which time First Coast was awarded a contract to serve as the MAC for Florida. Compl. ¶ 20; Answer ¶ 20.

8. To participate in the Medicare Part A program, providers must periodically submit a completed Form CMS-855A. The Form CMS-855A includes the following statement:

I agree to abide by the Medicare laws, regulations and program instructions that apply to this provider. The Medicare laws, regulations, and program instructions are available through the Medicare contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the provider's compliance with all applicable conditions of participation in Medicare.

CMS-855A, § 15, at 48, available at: <http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms855a.pdf> (Ex. 4); Compl. ¶ 21; Answer ¶ 21.

9. The certification statement requires at least one signature from an authorized official. That certification statement says:

I have read the contents of this application. My signature legally and financially binds this provider to the laws, regulations, and program instructions of the Medicare program. By my signature, I certify that the information contained herein is true, correct, and complete, and I authorize the Medicare fee-for-service contractor to verify this information. If I become aware that any information in this application is not true, correct, or complete, I agree to notify the Medicare fee-for-service contractor of this fact in accordance with the time frames established in 42 CFR § 424.520(b).

CMS-855A (Ex. 4), at 49; Compl. ¶ 21; Answer ¶ 21.

10. Halifax Hospital submitted Form CMS-855A several times from 2006 to 2010, agreeing each time to abide by all requirements of the Medicare Program. Rahn 30(b)(6) Depo. Tr. (April 11, 2013) (Ex. 5), at 94:10-15, 96:16-20, 112:19-23, 116:6-9, 117:14-18, 118:2-5. In filling out Form CMS-855A, Halifax undertook no steps to ensure compliance with the requirements of the Medicare Program. *Id.*, at 127:15-20.

11. Under the Medicare Part A Program, providers submit claims for institutional items and services rendered to patients on both an inpatient and outpatient basis using a Form UB-92 or, beginning on March 1, 2007, Form UB-04. Compl. ¶ 23; Answer ¶ 23.

12. Field 82 of Form UB-92 is called “Attending Phys. ID.” Form UB-92 (Ex. 6). The Medicare Claims Processing Manual (Claims Processing Manual) defines this field as “the clinician primarily responsible for the care of the patient from the beginning of the inpatient episode” for inpatient claims, and for outpatient claims as “the physician that requested the surgery, therapy, diagnostic tests or other services.” Claims Processing Manual (Ex. 7).

13. Field 83 of Form UB-92 is named “Other Phys. ID.” Form UB-92 (Ex. 6). The Claims Processing Manual defines “other physician” for inpatient claims as the physician who performed the principal procedure. If no principal procedure is performed, the hospital enters the UPIN and name of the physician who performed the surgical procedure most closely related to the principal diagnosis. If no procedure is performed, the hospital leaves this item blank.” For

outpatient claims, the “other physician” is defined as “the operating physician.” Claims Processing Manual (Ex. 7).

14. Field 76 of Form UB-04 is named “Attending.” Form UB-04 (Ex. 8). The Claims Processing Manual states: “Required when claim/encounter contains any services other than nonscheduled transportation services. If not required, do not send. The attending provider is the individual who has overall responsibility for the patient’s medical care and treatment reported in this claim/encounter.” Claims Processing Manual, Ch. 25 (Ex. 9), <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c25.pdf>.

15. The title of field 77 of Form UB-04 is “Operating.” Form UB-04 (Ex. 8). For the “Operating” field, the Claims Processing Manual states: “Required when a surgical procedure code is listed on this claim. If not required, do not send. The name and identification number of the individual with the primary responsibility for performing the surgical procedure(s).” Claims Processing Manual, Ch. 25 (Ex. 9).

16. From 2001 to 2011, Halifax Hospital submitted claims to First Coast for reimbursement by Medicare. Halifax’s Responses and Objections to United States’ Requests for Admission Nos. 230-240 (Ex. 10). When Halifax submitted UB-92 and UB-04 claims it was submitting those claims in accordance with all of the requirements of the Form CMS-855A. Rahn 30(b)(6) Depo. Tr. (March 19, 2013) (Ex. 5), at 37:20-25, 61:16-20.

17. For inpatient and outpatient claims, the physician identified by Halifax in field 82 of Form UB-92 and field 76 of Form UB-04 was the physician who established a plan of care for the patient. *Id.*, at 44:1-7, 57:10-17. Halifax also listed the admitting physician in field 76 of Form UB-04. Lewis 30(b)(6) Depo. Tr. (Ex. 11), at 49:10-25.

18. In field 83 of Form UB-92 Halifax indicated any physician performing a principal procedure on a patient. Rahn 30(b)(6) Depo. Tr. (March 19, 2013) (Ex. 5), at 44:8-15. Halifax indicated any operating physicians in Field 77 of Form UB-04. *Id.*, at 57:18-23.

19. Physicians and suppliers submit claims to Medicare using a Form 1500. Medicare Claims Processing Manual, Ch. 26 (Ex. 12), <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c26.pdf>. Field 17 of Form 1500 is “Name of Referring Provider or Other Source.” Form 1500 (Ex. 13). The Claims Processing Manual describes field 17 as “the name of the referring or ordering physician if the service or item was ordered or referred by a physician. All physicians who order services or refer Medicare beneficiaries must report this data.” Medicare Claims Processing Manual, Ch. 26 (Ex. 12).

20. Halifax Hospital used an entity called Halifax Healthcare Systems, Inc. to bill Medicare with a Form 1500. Rahn 30(b)(6) Depo. Tr. (March 19, 2013) (Ex. 5), at 69:6-8. Halifax Healthcare Systems, Inc. has submitted Form 1500 claims to Medicare from 2004 to 2009. *See* supporting data to expert report of Mr. Ian Dew (Ex. 14).

21. When Halifax submitted a Form 1500, the provider entered in field 17 was the physician who referred the patient for service. Rahn 30(b)(6) Depo. Tr. (March 19, 2013) (Ex. 5), at 69:15-20. Halifax’s general business definition of referral was “[t]he physician who is requesting service for the patient.” *Id.*, at 69:23-70:7.

22. ECFOI has submitted Form 1500 claims to Medicare from 2004 to 2009. *See* supporting data to expert report of Mr. Ian Dew (Ex. 14).

23. Halifax Staffing had employment agreements effective March 1, 2004 through February 28, 2009 (collectively, the contracts), with the following medical oncologists: Dr. Boon Chew, Dr. Walter Durkin, Dr. Ruby Anne Deveras, Dr. Abdul Sorathia, Dr. Richard Weiss, and

Dr. Gregory Favis (collectively, the Medical Oncologists). Halifax's Responses and Objections to United States' Request for Admission Nos. 265- 271 (Ex. 15).

24. The Medical Oncologists had a financial relationship with Halifax Hospital and made referrals to Halifax Hospital. Rousis Depo. Tr. (Nov. 1, 2012) (Ex. 16), at 240:13-23.

25. The contracts contained the following provision:

The Company shall pay to Employee as compensation for services the following:

c. Beginning with the fiscal year ending September 30, 2005, an equitable portion of an Incentive Compensation pool which is equal to 15% of the operating margin for the Medical Oncology program as defined by the financial statements produced by the Finance Department on a quarterly basis. The amount of the incentive compensation distributed to the Employee shall be determined by the Medical Oncology Practice Management Group. This compensation shall be paid annually according to the operating margin for the fiscal year.

E.g., HAL-1 0044568-80 (Ex. 17); Halifax's Responses and Objections to United States' Request for Admission Nos. 265-271 (Ex. 15). Halifax's fiscal year runs October 1 to September 30.

26. Operating Margin, as defined in the contracts, included: "revenue and direct expenses from outpatient medical oncology services. Revenue consisted of outpatient medical oncology services, physician services, and related outpatient oncology pharmacy charges." Halifax's Responses and Objections to United States' Interrogatory No. 6 (Ex. 18).

27. The Medical Oncologists treated patients at Halifax on an inpatient basis. *See* Durkin Depo. Tr. (Ex. 19), at 38:2-12. The treatment of a patient on an inpatient basis constitutes an inpatient hospital service. 42 C.F.R. § 411.351; Medicare Benefit Policy Manual, Chapter 6-10 (Ex. 21).

28. The Medical Oncologists treated patients at Halifax on an outpatient basis. *See* Durkin Depo. Tr., at 38:19-41:10 (Ex. 19). The treatment of a patient based on an outpatient

basis constitutes an outpatient hospital service. 42 C.F.R. § 411.351; Medicare Benefit Policy Manual, Chapter 6-20, 20.4, 20.6, 30 (Ex. 21).

29. The Medical Oncologists ordered or requested outpatient prescription drugs and certain other imaging services as part of a treatment plan for patients at Halifax.

30. By requesting the services identified in SUMF ¶¶ 27-29, the Medical Oncologists either: (1) requested the provision of Designated Health Services; (2) established a plan of care that included the provision of a Designated Health Service; (3) certified the need for a patient to receive a Designated Health Service; or (4) re-certified the need for a Designated Health Service. *See, e.g.,* Sorathia Depo. Tr. (Ex. 22), at 20:11-21; Weiss Depo. Tr. (Ex. 23), at 98:11-99:10.

31. Each time one of the Medical Oncologists performed a Medicare-reimbursable procedure on a Medicare beneficiary, Halifax submitted two claims for payment to the Medicare program: (1) one for the facility fee for that procedure; and (2) one for the professional component of the service. *See* Peburn 30(b)(6) Depo. Tr. (Ex. 1), at 221:6-22; 247:9-21; Rahn 30(b)(6) Depo. Tr. (March 19, 2013) (Ex. 5), at 27:25-28:3; 33:11-13.

32. From October 1, 2004 through February 28, 2009, Halifax submitted 1,496 claims to First Coast for inpatient services where one of the Medical Oncologists was listed as the attending or operating physician on the request for payment. *See* Declaration of Ian Dew (Ex. 36); supporting data to Dew expert report (Ex. 14); Halifax Objections and Responses to Requests for Admissions Nos. 233-237 (Ex. 24).

33. From October 1, 2004 through February 28, 2009, Halifax submitted 24,097 claims to First Coast for outpatient services where one of the Medical Oncologists was listed as the attending or operating physician on the request for payment. *See* Declaration of Ian Dew

(Ex. 36); supporting data to Dew expert report (Ex. 14); Halifax Objections and Responses to Requests for Admissions Nos. 233-37 (Ex. 24).

34. From October 1, 2004 through February 28, 2009, ECFOI submitted 6,735 claims to First Coast for services where one of the Medical Oncologists was listed as the rendering or referring provider on the request for payment. *See* Declaration of Ian Dew (Ex. 36); supporting data to Dew expert report (Ex. 14).

35. From October 1, 2004 through February 28, 2009, Halifax Health Care Systems, Inc. submitted 13,114 claims to First Coast for services where one of the Medical Oncologists was listed as the rendering or referring provider on the request for payment. *See* Declaration of Ian Dew (Ex. 36); supporting data to Dew expert report (Ex. 14).

36. First Coast reimbursed Halifax \$11,457,981 for the facility fees associated with Medicare inpatient procedures ordered by the Medical Oncologists from October 1, 2004 through February 28, 2009. *See See* Declaration of Ian Dew (Ex. 36); supporting data to Dew expert report (Ex. 14).

37. First Coast reimbursed Halifax \$19,393,003 for the facility fees associated with Medicare outpatient procedures ordered by the Medical Oncologists from October 1, 2004 through February 28, 2009. *See See* Declaration of Ian Dew (Ex. 36); supporting data to Dew expert report (Ex. 14).

38. First Coast reimbursed ECFOI \$2,372,825 for the DHS associated with Medicare procedures ordered by the Medical Oncologists from October 1, 2004 through February 28, 2009. *See* Declaration of Ian Dew (Ex. 36); supporting data to Dew expert report (Ex. 14).

39. First Coast reimbursed Halifax Health Care Systems, Inc. \$1,044,858 for DHS associated with Medicare procedures ordered by the Medical Oncologists from October 1, 2004

through February 28, 2009. *See* Declaration of Ian Dew (Ex. 36); supporting data to Dew expert report (Ex. 14).

40. For Halifax's fiscal years 2005 through 2009, each of the Medical Oncologists received a bonus based on the operating margin of Halifax's medical oncology program. *See* Garthwaite Depo. Tr. (May 1, 2012) (Ex. 25), at 72:10-13; Halifax Responses and Objections to United States' Requests for Admissions Nos. 175-198 (Ex. 26).

41. The Operating Margin of the medical oncology program was determined by subtracting direct expenses from revenue for outpatient medical oncology services. *See* Halifax Objection and Response to United States' Interrogatory No. 6 (Ex. 18); Garthwaite Depo. Tr. (May 1, 2012) (Ex. 25), at 69:25-70:3.

42. Halifax distributed the Operating Margin bonus to each Medical Oncologist based on a formula that calculated the percentage of personally performed services completed by the individual Medical Oncologist as compared to the personally performed services completed by all Medical Oncologists for the time period in question. *See* Garthwaite Depo. Tr. (May 1, 2012) (Ex. 25), at 127:23-129:16; Peburn 30(b)(6) Depo. Tr. (Ex. 1), at 204:12-205:3.

43. The Operating Margin for the medical oncology program varied based on "what's happening with the program." Garthwaite Depo. Tr. (May 1, 2012) (Ex. 25), at 93:21-94:5; *see* Rousis Depo. Tr. (Feb. 19, 2013) (Ex. 16), at 446:10-448:1. As the Operating Margin increased, the physician compensation pool paid to the Medical Oncologists increased as well. *See* Garthwaite Depo. Tr. (May 1, 2012) (Ex. 25), at 94:6-10.

44. In Fiscal Year 2005, the Operating Margin for the medical oncology program was \$1,541,564, and the physician incentive compensation pool (comprising fifteen percent of the operating margin) was \$231,234.60. HAL-1 0325436 (Ex. 35). In Fiscal Year 2006, the

Operating Margin for the medical oncology program was \$1,935,015, and the physician incentive compensation pool was \$290,252.25. HAL-1 0325344 (Ex. 35). In Fiscal Year 2007, the Operating Margin for the medical oncology program was \$1,492,933.77, and the physician incentive compensation pool was \$223,940.07. HAL-1 0325269 (Ex. 35). In Fiscal Year 2008, the Operating Margin of the medical oncology program was \$1,699,886, and the physician incentive compensation pool was \$254,983. HAL-1 0325216 (Ex. 35).

45. Halifax's chief compliance officer, George Rousis, sent Halifax executives periodic updates regarding developments related to the Stark Law. *See* HAL-1_0013349-75 (Ex. 32). In a summary dated March 24, 2004, Mr. Rousis advised Halifax leadership that the Stark Law precluded the payment of bonuses based on referrals for ancillary services. *Id.*, at HAL-1_0013352. Mr. Rousis recognized that Medicare could not reimburse providers for any DHS provided pursuant to a referral by a physician who maintained a prohibited financial arrangement with a DHS provider. *See* Rousis Depo. Tr. (Nov. 1, 2012) (Ex. 16), at 252:17-253:10.

46. In October 2008, relator Elin Baklid-Kunz, who is not an attorney, attended a conference in Philadelphia sponsored by the Health Care Compliance Association. *See* Baklid-Kunz Depo. Tr. (Aug. 20, 2012) (Ex. 27), at 72:24-73:9; 75:6-76:7. At the October 2008 conference, Ms. Baklid-Kunz attended presentations regarding the Stark Law. *See* Baklid-Kunz Depo. Tr. (April 4, 2013) (Ex. 27), at 206:23-207:4.

47. Prior to October 2008, Ms. Baklid-Kunz's only Stark Law training consisted of watching an hour-long computer-based PowerPoint training presentation available on Halifax's internal website. *See* Baklid-Kunz Depo. Tr. (April 4, 2013) (Ex. 27), at 206:7-12.

48. Based on information presented in the PowerPoint she watched at Halifax and the presentations at the October 2008 conference, Ms. Baklid-Kunz concluded that the employment

agreements between Halifax Staffing and the Medical Oncologists may violate the Stark Law.

See Baklid-Kunz Depo. Tr. (April 4, 2013) (Ex. 27), at 212:9-21.

49. Ms. Baklid-Kunz advised Ms. Audrey Pike, then-Associate General Counsel of Halifax, of her view that the Medical Oncology employment agreements violated the Stark Law in approximately October or November 2008. See HAL-1 0691036 (Ex. 28); Baklid-Kunz Depo. Tr. (April 4, 2013) (Ex. 27), at 207:10-208:10; Pike Depo. Tr. (Ex. 29), at 23:19-25:11.

50. In 2008, Halifax determined that the Medical Oncology employment agreements “are not permitted under the STARK regulations.” HAL-1 0691036-38 (Ex. 28); HAL-1 0691071-72 (Ex. 30); see Baklid-Kunz Depo. Tr. (Aug. 20, 2012)(Ex. 27), at 71:7-19; 72:4-19; 97:16-98:1; see Garthwaite Depo. Tr. (Feb. 19, 2013) (Ex. 25), at 333:2-334:4.

51. After determining that the Medical Oncologists’ employment agreements violated the Stark Law, Halifax deemed it necessary to amend the employment agreements. See Garthwaite Depo. Tr. (May 1, 2012) (Ex. 25), at 119:6-13.

52. Despite determining that the Medical Oncology employment agreements violated the Stark Law at some point in 2008, Halifax nevertheless paid the Medical Oncologists a bonus in March 2009 pursuant to the terms of their employment agreements. See Baklid-Kunz Depo. Tr. (Aug. 20, 2012) (Ex. 27), at 70:14-71:6; 98:20-101:16; PTF 0010062 (Ex. 31).

53. Halifax amended the Medical Oncology employment agreements in 2010, with a retroactive contract start date of March 1, 2009. See Weiss Depo. Ex. 6 (Ex. 23).

III. SUMMARY OF ARGUMENT

The Stark Law prohibits providers from having financial relationships with physicians who refer patients to that provider for designated health services. If a provider has a financial relationship with a physician, then the provider cannot submit claims for referred services to

Medicare unless an exception to the Stark Law applies. If a provider cannot demonstrate that it meets all the requirements of a Stark Law exception, then Medicare cannot pay any claims submitted by that provider for designated health services referred by the physician. All claims submitted to Medicare in violation of the Stark Law constitute an overpayment that the United States is entitled to recoup. If the provider knowingly (that is, with actual knowledge, with deliberate ignorance, or in reckless disregard of the law) violates the Stark Law and submits claims for payment to Medicare, then that provider also violates the False Claims Act.

As set forth in this Motion for Partial Summary Judgment, Halifax violated the Stark Law from 2005 through 2009, and did so knowingly. Halifax paid bonuses to six physicians based on the amount of services those physicians referred to Halifax Hospital. Halifax's actions are exactly what the Stark Law was enacted to prevent: physicians basing referral decisions on financial gain rather than a patient's best interests. Section IV sets forth the Stark Law and regulations and explains how the Stark Law is applicable to Halifax and that Halifax cannot meet either of the exceptions raised in its Answer to the Complaint in Intervention. Section V outlines Halifax's liability on the United States' common law claims of unjust enrichment and payment by mistake. Section VI discusses Halifax's liability under the False Claims Act and sets forth the evidence that Halifax acted with knowledge that it was violating the Stark Law. Finally, Section VII sets forth the bases for summary judgment on six of Halifax's eight affirmative defenses.

IV. THE STARK LAW AND REGULATIONS

The Stark Law, 42 U.S.C. § 1395nn, prohibits health care providers from submitting claims for payment to the Medicare program based on patient referrals from physicians having a statutorily prohibited financial relationship with the hospital. Prior to the passage of the Stark Law, academic studies had shown that when physicians had a financial relationship with a

facility, they referred more patients to that facility than they would have in the absence of such a relationship. *See* Medicare and Medicaid Programs; Physicians' Referrals to Health Care Entities with Which They Have Financial Relationships, 66 Fed. Reg. 856, 859 (Jan. 4, 2001). The Stark Law was designed to protect the integrity of the Medicare program by preventing a doctor's personal financial interests from influencing his or her medical decision-making and ensuring that such decisions were based solely on the best interests of the patient.

Congress enacted the Stark Law in two parts, commonly known as Stark I and Stark II. Stark I applies to referrals of Medicare patients for clinical laboratory services made on or after January 1, 1992, by physicians with a prohibited financial relationship with the clinical lab provider. *See* Omnibus Budget Reconciliation Act of 1989, P.L. 101-239, § 6204. Stark II extends the law to referrals for ten additional types of health services, including inpatient and outpatient hospital services. *See* Omnibus Reconciliation Act of 1993, P.L. 103-66, § 13562, Social Security Act Amendments of 1994, P.L. 103-432, § 152. At all times relevant to this action, the Stark Law has applied to referrals for designated health services, including inpatient and outpatient hospital services, by physicians with a prohibited financial relationship with a hospital. *See* 42 U.S.C. § 1395nn(h)(6).

A. General Prohibitions Established by the Stark Law

The Stark Law establishes the clear rule that the United States will not pay for items or services ordered by physicians who have improper financial relationships with a hospital. *See U.S. ex rel. Drakeford v. Tuomey Healthcare Sys., Inc.*, 675 F.3d 394, 397 (4th Cir. 2012); *United States v. Rogan*, 459 F. Supp. 2d 692, 711 (N.D. Ill. 2006), *aff'd* 517 F.3d 449 (7th Cir. 2008). In pertinent part, the Stark Law provides:

Except as provided in subsection (b) of this section, if a physician (or an immediate family member of such physician) has a financial relationship with an entity specified in paragraph (2), then –

(A) the physician may not make a referral to the entity for the furnishing of designated health services for which payment otherwise may be made under this subchapter, and

(B) the entity may not present or cause to be presented a claim under this subchapter or bill to any individual, third party payor, or other entity for designated health services furnished pursuant to a referral prohibited under subparagraph (A).

42 U.S.C. § 1395nn (a)(1). Designated Health Services (DHS) are listed in section (h) of the statute and include inpatient and outpatient hospital services and radiology services. *See* 42 U.S.C. § 1395nn(h)(6). In addition to prohibiting hospitals from submitting claims for DHS under these circumstances, the Stark Law also prohibits payment by the Medicare program of such claims: “No payment may be made under this subchapter for a designated health service which is provided in violation of subsection (a)(1) of this section.” 42 U.S.C. § 1395nn(g)(1).

B. Pertinent Definitions

The Stark Law broadly defines prohibited financial relationships to include “compensation arrangements” in which any “remuneration” is paid “directly or indirectly, in cash or in kind,” by a hospital to a referring physician. *See* 42 U.S.C. § 1395nn(a)(2)(B), (h)(1); 42 C.F.R. § 411.354(c). The regulations identify two types of compensation arrangements that are subject to the Stark prohibitions: direct and indirect. A direct compensation arrangement exists if remuneration passes between the hospital and the referring physician (or his or her family member) without going through any intervening persons or entities. 42 C.F.R. §§ 411.354(a), (c)(1). An indirect compensation arrangement exists when the following circumstances are present:

(1) between the referring physician (or immediate family member) and the hospital, there is an unbroken chain of any number of persons or entities that have financial relationships between them (whether an ownership or investment interest or a compensation arrangement);

(2) the referring physician (or immediate family member) receives aggregate compensation from the person or entity within the chain with which the physician (or immediate family member) has a direct financial relationship that varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the hospital; and

(3) the hospital has actual knowledge of, or acts in reckless disregard or deliberate ignorance of the fact that the compensation arrangement with the physician (or family member) varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the hospital.

42 C.F.R. § 411.354(c)(2).²

The Stark Law defines “referral” as “the request or establishment of a plan of care by a physician which includes the provision of designated health services.” 42 U.S.C.

§ 1395nn(h)(5)(A). The accompanying regulations interpreting the statute also broadly define “referral” as, among other things, “a request by a physician that includes the provision of any designated health service for which payment may be made under Medicare, the establishment of a plan of care by a physician that includes the provision of such a designated health service, or the certifying or recertifying of the need for such a designated health service” 42 C.F.R. § 411.351. A referring physician is defined as “a physician who makes a referral as defined in this section or who directs another person or entity to make a referral or who controls referrals made to another person or entity.” *Id.*

When a physician performs a procedure at a facility, the entity submits two bills to Medicare: one for the physician’s personally performed service and one for the facility fee. The

² In 2007, the Department of Health and Human Services altered the language of the second element of the definition to replace “otherwise reflects” with “takes into account.” 72 Fed. Reg. 51012, 51087 (Sept. 5, 2007). The Department of Health and Human Services explained that it was doing so to make the language more consistent with other parts of the regulation, but that the change was “non-substantive.” *Id.* at 51027.

facility fee, also known as the “facility component” or “technical component” is submitted by the entity to Medicare on a Form UB-92 or UB-04, depending on which form was in effect when the service occurred. In promulgating the Stark regulations, CMS responded to a comment about exclusion of personally performed services by explaining:

We have concluded that when a physician initiates a designated health service and personally performs it him or herself, that action would not constitute a referral of the service to an entity However, in the context of inpatient and outpatient hospital services, there would still be a referral of any hospital service, technical component, or facility fee billed by the hospital in connection with the personally performed service. Thus, for example, in the case of an inpatient surgery, there would be a referral of the surgical service, even though the referring physician personally performs the service. If the referring physician has a financial relationship with the hospital, that relationship must fit in an exception.

66 Fed. Reg. 856, 941 (Jan. 4, 2001). Applying CMS’s guidance, the Fourth Circuit found that “the facility component of the physicians’ personally performed services, and the resulting facility fee billed by Tuomey based upon that component” was a referral, and was therefore prohibited by the Stark Law if there was a financial relationship between the physician and the entity. *Tuomey Healthcare Sys.*, 675 F.3d at 407.

The physician identified on the UB-92 claim form in box 82 (“attending phys. ID”) and box 83 (“other phys. ID”) is the referring physician under the Stark Law. *Rogan*, 459 F. Supp. 2d at 713-14. For inpatient claims, the physician identified in box 82 is “the clinician primarily responsible for the care of the patient from the beginning of the inpatient episode”; for outpatient claims, the physician identified in box 82 is “the physician that requested the surgery, therapy, diagnostic tests or other services.” Claims Processing Manual (Ex. 7). For inpatient claims, an entity is required to fill out box 83 “if a procedure is performed” and must enter identifying information for “the physician who performed the principal procedure.” *Id.* For outpatient claims, the entity populates box 83 with identifying information for the “operating physician.”

Id. “These manual provisions were adopted to meet Congress’s requirement that the identification number of referring physicians be reported with claims made to Medicare.”

Rogan, 459 F. Supp. 2d at 713-14 (*citing* Hospital Manual, Transmittal No. 637, May 1, 1992).

Applying the Stark Law to the current claims manual and form, the physicians identified in boxes 76 and 77 of the UB-04 claim form are referring physicians under the Stark Law. The physician the entity identifies in box 76 of the UB-04 form is described as “the individual who has overall responsibility for the patient’s medical care and treatment reported in this claim/ encounter.” Claims Processing Manual (Ex. 9). The physician the entity identifies in box 77 of the UB-04 form is “the individual with the primary responsibility for performing the surgical procedure(s).” *Id.* Just as the definitions for the form UB-92 were adopted to implement the requirement that entities identify referring physicians, so were the definitions for the form UB-04 adopted. *Cf. Rogan*, 459 F. Supp. 2d at 713-14.

Non-institutional claims are submitted on a Form 1500. SUMF ¶ 19. Box 17 of Form 1500 is “Name of Referring Provider or Other Source.” *Id.* The Claims Processing Manual describes box 17 as “the name of the referring or ordering physician if the service or item was ordered or referred by a physician. All physicians who order services or refer Medicare beneficiaries must report this data.” *Id.*

C. Statutory and Regulatory Exceptions

The Stark Law and its regulations define specific exceptions to the general referral and billing prohibitions. In order to avoid the referral and billing prohibitions, a hospital must, by a preponderance of the evidence, demonstrate that an exception applies. *U.S. ex rel. Kosenske v. Carlisle HMA, Inc.*, 554 F.3d 88, 95 (3rd Cir. 2009); *Rogan*, 459 F. Supp. 2d at 716. In its Answer to the Complaint in Intervention, Halifax asserted the following affirmative defense:

Exceptions to the Stark Law: Insofar as any of the United States' causes of action in the Complaint allege violations of the Stark Law; the employment agreements at issue meet the requirements of the Bona Fide Employee Exception, or, in the alternative, the Indirect Compensation Exception to the statute. Accordingly, no financial relationship within the meaning of the Stark Law exists.

Answer to Complaint in Intervention, Affirmative Defenses, ¶ 8.

1. Indirect Compensation Exception

Where an indirect compensation arrangement exists, referrals are prohibited unless the compensation arrangement satisfies all the following conditions:

(a) "The compensation received by the physician . . . is fair market value for services and items actually provided and not determined in any manner that takes into account the value or volume of referrals or other business generated by the referring physician" for the hospital.

(b) The compensation arrangement must be in writing, signed by the parties, specifying the services covered by the agreement, except in the case of a bona fide employment relationship, "in which case the agreement need not be in writing, but must be for identifiable services and be commercially reasonable even if no referrals are made to the employer."

(c) The compensation does not violate the Anti-Kickback Statute or any other federal or state law regarding billing and claims submission.

42 C.F.R. § 411.357(p).

2. Bona Fide Employment Exception

The bona fide employment exception is available where a direct compensation arrangement exists if the following conditions are met:

(a) The employment agreement must be for identifiable services.

(b) The remuneration for the employment must be set in advance, consistent with fair market value for the services provided and "not determined in a manner that takes into account (directly or indirectly) the volume or value of any referrals by the referring physician." However, the exception generally allows payment of remuneration in the form of a productivity bonus based on services personally performed by the employed physician.

(c) The remuneration must be provided under an agreement that would be commercially reasonable even if no referrals were made to the employer.

42 U.S.C. § 1395nn(e)(3); 42 C.F.R. § 411.357(c).

Both the Bona Fide Employee and the Indirect Compensation exceptions require that the amount of remuneration paid to the physician is not determined in a manner that directly or indirectly takes into account the volume or value of any referrals by the referring physician. 42

C.F.R. § 411.357(c), (p). CMS provided the following guidance in response to a comment:

Comment: Commenters also wished us to clarify whether the following arrangements take into account the volume or value of referrals or other business generated between the parties: (1) Payments based on a percentage of gross revenues; (2) payments based on a percentage of collections; (3) payments based on a percentage of expenses; and (4) payments based on a percentage of a fee schedule.

Response: A compensation arrangement does not take into account the volume or value of referrals or other business generated between the parties if the compensation is fixed in advance and will result in fair market value compensation, and the compensation does not vary over the term of the arrangement in any manner that takes into account referrals or other business generated. The first three arrangements described by the commenters are neither aggregated fixed compensation amounts, nor fixed “per service,” “per use,” or “per time period” amounts. Percentage compensation that is determined by calculating a percentage of a fluctuating or indeterminate amount, such as revenues, collections, or expenses, is not fixed in advance. Accordingly, the first three arrangements do not meet the requirement that compensation be fixed in advance.

66 Fed. Reg. 856, 877-78 (Jan. 4, 2001).

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If a relationship between a physician and a hospital does not meet one of the exceptions in the statute or the regulations, the hospital is prohibited from billing Medicare for any DHS referred by that physician, regardless of the legality of the physician’s other business at the hospital. 42 U.S.C. § 1395nn(a)(1), (g)(1); *Roberts v. Aging Care Home Health, Inc.*, 474 F. Supp. 2d 810, 815 (W.D. La. 2007). If a hospital submits prohibited claims and collects

payment, the Stark regulations expressly require that any entity collecting payment for a healthcare service “performed under a prohibited referral must refund all collected amounts on a timely basis.” 42 C.F.R. § 411.353.

V. THE UNITED STATES IS ENTITLED TO SUMMARY JUDGMENT ON ITS CLAIMS FOR PAYMENT BY MISTAKE AND UNJUST ENRICHMENT BASED ON HALIFAX’S VIOLATION OF THE STARK LAW

The United States’ payment by mistake theory is premised upon the long-standing principle that “[t]he Government by appropriate action can recover funds which its agents have wrongfully, erroneously, or illegally paid. ‘No statute is necessary to authorize the United States to sue in such a case. The right to sue is independent of statute. . . .’” *United States v. Wurts*, 303 U.S. 414, 415-16 (1938) (footnote omitted) (quoting *United States v. Bank of the Metropolis*, 15 Pet. 377, 401 (1841)). Further, “the Government’s right to recover funds, from a person who received them by mistake and without right, is not barred unless Congress has ‘clearly manifested its intention’ to raise a statutory barrier.” *Wurts*, 303 U.S. at 416 (citation omitted). To prevail on a claim for payment by mistake, “the Government must show that the . . . program ‘made . . . payments under an erroneous belief which was material to the decision to pay.’” *Roberts*, 474 F. Supp. 2d at 818 (citation omitted).

The United States is also pursuing a recovery for funds obtained by Halifax in violation of the Stark Law under the theory of unjust enrichment. To prevail under this theory, the United States must show that: (1) the government had a reasonable expectation of payment; (2) the defendant should reasonably have expected to pay, or (3) “society’s reasonable expectations of person and property would be defeated by nonpayment.” *Provident Life & Accident Ins. Co. v. Waller*, 906 F.2d 985, 993-94 (4th Cir. 1990); accord *Rogan*, 459 F. Supp. at 728. Significantly for this case, “where the disbursement of public funds is concerned, the government is not under

the obligation of showing either that the recipient was unjustly enriched or that the balance of equities otherwise lies in its favor.” *Mt. Vernon Co-op Bank v. Gleason*, 367 F.2d 289, 291 (1st Cir. 1996). This principle has been widely recognized for over a century. See *United States v. Burchard*, 125 U.S. 176, 181 (1888) (mistaken overpayment of retirement funds by U.S. Navy “may be corrected”); *United States v. Lahey Clinic Hosp., Inc.*, 399 F.3d 1, 15–16, n.16 (1st Cir. 2005) (United States has a “longstanding” right to recover Medicare overpayments).

Given that the Stark Law prohibits payment for any DHS referred by a physician with whom the entity performing the DHS has a prohibited financial relationship, the United States could not have lawfully paid Halifax if it had been apprised of the financial relationship between Halifax and the Medical Oncologists. The United States therefore is entitled to recover all amounts paid to Halifax for these services. Similarly, because the employment agreements between Halifax and the Medical Oncologists violated the Stark Law, Halifax was unjustly enriched in the amount of the Medicare reimbursements paid by the United States for DHS ordered by the Medical Oncologists. The United States is therefore entitled to summary judgment on its common law claims of payment by mistake and unjust enrichment based on Halifax’s violation of the Stark Law.

A. The Medical Oncologists had a Financial Relationship with Halifax Hospital Medical Center from 2004-2009

As described above, in order for there to exist a financial relationship between an entity and a physician there must be either an indirect or direct employment relationship. There is no dispute that Halifax Hospital is an entity that provides DHS to Medicare beneficiaries. There is no dispute that the Medical Oncologists had employment agreements with Halifax Staffing from 2004 through 2009, and that the Medical Oncologists had financial relationships with Halifax Hospital. SUMF ¶¶ 23-24. There is no dispute that the Medical Oncologists received

remuneration from a Halifax Staffing account. SUMF ¶¶ 2-3, 44. Because Halifax Staffing is a separate legal entity, there existed an indirect compensation relationship between the Medical Oncologists and Halifax Hospital.³

B. The Medical Oncologists made Referrals for DHS to Halifax Hospital Medical Center from 2004-2009

There is no dispute that the Medical Oncologists performed services at Halifax Hospital on inpatient and outpatient bases. SUMF ¶¶ 27-29. There is no dispute that Halifax Hospital submitted claims to First Coast for reimbursement by Medicare for the facility fees associated with the Medical Oncologists' inpatient and outpatient services provided to Medicare beneficiaries. SUMF ¶ 31. The chief compliance officer at Halifax Hospital admits that the Medical Oncologists referred patients to Halifax Hospital. SUMF ¶ 24. Applying the agency guidance and the *Tuomey* Fourth Circuit opinion, all of the technical components associated with the Medical Oncologists' inpatient and outpatient services are referrals. 66 Fed. Reg. 856, 941 (Jan. 4, 2001); *Tuomey Healthcare Sys.*, 675 F.3d at 407.

There is no dispute that Halifax Hospital identified the Medical Oncologists in boxes 82 and 83 of Forms UB-92 and in boxes 76 and 77 of Forms UB-04 submitted to First Coast from 2004-2009. There is no dispute that for inpatient and outpatient claims, the physician identified by Halifax in field 82 of Form UB-92 and field 76 of Form UB-04 was the physician who established a plan of care for the patient. SUMF ¶ 17. There is no dispute that in field 83 of Form UB-92 Halifax would indicate any physician performing a principal procedure on a patient. SUMF ¶ 18. There is no dispute that in field 83 of Form UB-92 Halifax would indicate any physician performing a principal procedure on a patient, and that Halifax indicates any operating

³ Halifax does not dispute that the Medical Oncologists had an employment relationship with Halifax Hospital, but responded in its Answer that the relationship was direct rather than indirect. As discussed in section V.C, *infra*, it is irrelevant whether the employment relationship is direct or indirect because under either circumstance Halifax cannot meet the requirements of any exception.

physicians in Field 77 of a Form UB-04. *Id.* There is no dispute that Medicare paid these claims. SUMF ¶¶ 32-33, 36-37.

There is no dispute that Halifax, through the entity Halifax Healthcare Systems, Inc., submitted Forms 1500 to First Coast. SUMF ¶ 20. There is no dispute that Halifax identified the Medical Oncologists in box 17 of Forms 1500 submitted to First Coast. SUMF ¶ 35. There is no dispute that Halifax, as the Claims Processing Manual required, identified the physician ordering the service in box 17 of the Forms 1500. SUMF ¶ 21. There is no dispute that Medicare paid the claims submitted by Halifax Healthcare Systems, Inc. that identified a medical oncologist as the referring physician. SUMF ¶ 39.

There is no dispute that Halifax has an ownership interest in ECFOI. SUMF ¶ 4. There is no dispute that ECFOI submitted Forms 1500 for payment by Medicare to First Coast. SUMF ¶¶ 22, 34. There is no dispute that ECFOI identified the Medical Oncologists in box 17 of Forms 1500. SUMF ¶ 34. There is no dispute that the Claims Processing Manual required that the physician identified in box 17 of Form 1500 be the physician who ordered the service. SUMF ¶ 19. There is no dispute that Medicare paid these claims. SUMF ¶ 38.

Because the physician identified in box 82 of Form UB-92, box 83 of Form UB-92, box 76 of Form UB-04, box 77 of Form UB-04, and box 17 of a Form 1500 is a referring physician, the Medical Oncologists were referring physicians for all claims in which they were identified in one of those boxes.

C. The Medical Oncologists' Employment Agreements Took Into Account the Volume or Value of Referrals

Because there is no dispute that the Medical Oncologists had a financial relationship with Halifax Hospital and made referrals for DHS to Halifax Hospital, all claims submitted by Halifax Hospital to First Coast for payment by Medicare were not payable, unless an exception to the

Stark Law applies. Halifax raised two exceptions in its Answer to the Complaint in Intervention: the Bona Fide Employee exception and the Indirect Compensation exception. Because the Medical Oncologists' employment agreements took into account the volume or value of referrals to Halifax Hospital, Halifax cannot meet the requirements of either exception.

It is undisputed that the Medical Oncologists' employment agreements called for a distribution of "an equitable portion of an Incentive Compensation pool which is equal to 15% of the operating margin for the Medical Oncology program as defined by the financial statements produced by the Finance Department on a quarterly basis." SUMF ¶ 25. It is undisputed that the operating margin included the following components: "outpatient medical oncology services, physician services, and related outpatient oncology pharmacy charges." SUMF ¶ 26. It is undisputed that the Medical Oncologists were compensated according to the terms of this agreement. SUMF ¶¶ 40, 44. It is undisputed that this incentive compensation was not fixed in advance. SUMF ¶ 43. It is undisputed that two elements of this incentive compensation, outpatient prescription drugs and outpatient services, are DHS. 42 U.S.C. § 1395nn(h)(6)(J)-(K); SUMF ¶ 26.

Therefore, the incentive compensation paid to the Medical Oncologists varied with the volume or value of referrals, and Halifax cannot meet the requirements of either the Bona Fide Employee or Indirect Compensation exception.

D. Stark Law Damages

The Stark Law prohibition on Medicare payment for DHS provided in violation of the statute, *see* 42 U.S.C. § 1395nn(g)(1), entitles the United States to recover damages in this matter based on the common law principal of unjust enrichment or payment by mistake equal to the

amount paid for DHS referred to Halifax by the Medical Oncologists for the entire period the Medical Oncologists' employment agreements violated the law.

As established in *Tuomey* and *Rogan*, the statutory and regulatory definition of referral encompasses Medicare claims for facility fees on which a physician with whom an entity has a prohibited financial relationship is identified as the attending or operation physician. *Tuomey Healthcare Sys.*, 675 F.3d, at 407; *Rogan*, 459 F. Supp. 2d, at 713-14. Applying the same definition of referral to this case, the uncontroverted factual record shows that Halifax improperly received Medicare reimbursements totaling \$34,268,667 from 45,442 claims⁴ for DHS referrals generated by the Medical Oncologists in violation of the Stark Law from October 1, 2004 through February 28, 2009. SUMF ¶¶ 32-39. The number and value of the claims was determined by Ian Dew, the government's expert in the field of Medicare claims analysis.

As set forth in Mr. Dew's expert report, the CMS Office of Information Systems provided three datasets containing Medicare Part A inpatient, Medicare Part B outpatient, and Medicare Part B non-institutional outpatient claims. See Expert Report of Ian Dew (Ex. 14), at 3-4. Mr. Dew filtered the Medicare institutional claims data to isolate only those claims where a physician named in the United States' Complaint in Intervention was identified as the attending or operating physician on the claim submitted by Halifax. See *id.*, at 4. Halifax's own claims analysis expert, Mr. Donald Moran, validated this approach, and was able to replicate Mr. Dew's analysis to within 0.02 percent. See Expert Report of Mr. Donald Moran (Ex. 20), at 12 (Table 1) and Att. 4. Mr. Dew used a similar process to identify only those non-institutional outpatient claims submitted by ECFOI or Halifax Healthcare Systems, Inc. where a physician named in the

⁴ This number is the total number of claims for inpatient and outpatient hospital services submitted by Halifax Hospital where one of the Medical Oncologists is listed as either the attending or operating physician and claims submitted by ECFOI and Halifax Healthcare Systems, Inc. where one of the Medical Oncologists is identified as the referring physician for the period October 1, 2004 through February 28, 2009.

United States' Complaint in Intervention was identified as the referring physician on the claim submitted by Halifax or an entity affiliated with Halifax. The United States, through the supporting data to Mr. Dew's report, has identified the specific claims for DHS services referred by each of the Medical Oncologists while the contracts violated the Stark Law. The United States will provide this same information to the Court upon request.

As set forth in section IV.B, the United States requests that this Court follow the holding and rationale articulated in *Rogan* and *Tuomey*. As Judge Easterbrook explained in *Rogan*, "[t]he government offers a subsidy (from the patient's perspective, a form of insurance), with conditions. When the conditions are not satisfied, nothing is due. Thus the entire amount that [defendant] received of these . . . claims must be paid back." 517 F.3d at 453. The United States is therefore entitled to summary judgment under the theory of unjust enrichment or payment by mistake in the amount of \$34,268,667.

VI. THE UNITED STATES IS ENTITLED TO SUMMARY JUDGMENT UNDER MULTIPLE PROVISIONS OF THE FALSE CLAIMS ACT

The False Claims Act, 31 U.S.C. §§ 3729, *et seq.* (FCA), is one of the United States' most important tools for combating fraud against the federal government. Enacted in 1863 in response to fraud during the Civil War, the FCA has been amended several times to bolster the fight against false claims for payment made to the United States. The statute was intended "to reach all types of fraud, without qualification, that might result in financial loss to the Government." *United States v. Niefert-White*, 390 U.S. 228, 232 (1968). Many courts have held that the statute should be construed "broadly" or "expansively" to accomplish the statute's remedial goal of protecting public funds from false and fraudulent claims. *See e.g., United States ex rel. Clausen v. Lab. Corp. of America, Inc.*, 290 F.3d 1301, 1307 (11th Cir. 2002).

A violation of the FCA occurs, *inter alia*, when any person “knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval,” 31 U.S.C.

§ 3729(a)(1)(A).⁵ Liability under this section of the FCA requires plaintiffs to demonstrate: “(1) a false or fraudulent claim; (2) which was presented, or caused to be presented, by the defendant to the United States for payment or approval; and (3) with the knowledge that the claim was false.” *United States ex rel. Walker v. R & F Properties of Lake Cty., Inc.*, 433 F.3d 1349, 1355 (11th Cir. 2005).

The FCA also imposes liability on a person who “knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government.” 31 U.S.C. § 3729(a)(2)(2003); *Hopper v. Solvay Pharmaceuticals, Inc.*, 588 F.3d 1318, 1327 (11th Cir. 2009).⁶ In order to establish a violation of this section, the government must establish “that (1) the defendant made a false record or statement for the purpose of getting a false claim paid or approved by the government; and (2) the defendant’s false record or statements caused the government to actually pay a false claim, either to the defendant itself, or to a third party.” *Hopper*, 588 F.3d at 1327.

In addition, 31 U.S.C. § 3729(a)(1)(G), also known as the FCA’s “reverse false claim” provision, prohibits the use of false statements to conceal or avoid an obligation to pay money to

⁵ The FCA was amended by the Fraud Enforcement and Recovery Act of 2009, Pub.L. 111-21, May 20, 2009, 123 Stat.1617. The amendments apply to conduct on or after May 20, 2009, except that section 3729(a)(1)(B) is effective June 7, 2008; also, § 3731(b) is effective for all matters pending on May 20, 2009.

⁶ The United States respectfully disagrees with the footnote in *Hopper* stating that § 3729(a)(1)(B) applies only to claims for payment, rather than legal claims, pending on or after June 7, 2008, and instead believes that the better interpretation is that § 3729(a)(1)(B) was made applicable to all pending cases. See *U.S. ex rel. Sanders v. Allison Engine Co.*, 703 F.3d 930, 941-42 (6th Cir. 2012) (“using the technical definition in context (‘claims under the False Claims Act’) provides a strained reading”). Consistent with *Hopper*, however, the United States is relying on the old version of the statute, because the majority of the claims at issue in this Motion were not pending as of June 7, 2008, and since application of the old version makes no difference in this case.

the United States. To establish a claim under this section, the government must prove: “(1) a false record or statement and (2) the defendant’s knowledge of the falsity; (3) that the defendant made, used or caused to be made or used a false statement or record; (4) for the purpose to conceal, avoid, or decrease an obligation to pay money to the government; and (5) the materiality of the misrepresentation.” *United States ex rel. Matheny v. Medco Health Solutions, Inc.*, 671 F.3d 1217, 1222 (11th Cir. 2012) (citing *United States v. Bourseau*, 531 F.3d 1159, 1164 (9th Cir. 2008)).

With respect to each provision of the FCA, knowledge is defined as: (1) having actual knowledge of the information; (2) acting in deliberate ignorance of the truth or falsity of the information; or (3) acting in reckless disregard of the truth or falsity of the information. 31 U.S.C. § 3729(b)(1). Under the FCA, no proof of specific intent is required. *Id.*, § 3729(b)(1)(B). In defining knowledge for FCA purposes, “Congress adopted ‘the concept that individuals and contractors receiving public funds have some duty to make a limited inquiry so as to be reasonably certain they are entitled to the money they seek.’” *United States v. Kaman Precision Products, Inc.*, No. 6:09-cv-1911-Orl-31GJK, at *4, 2011 WL 3841569 (M.D. Fla. Aug. 30, 2011) (quoting S. Rep. No. 99-345, at 20 (1986)). The knowledge standard was designed “to preclude ‘ostrich’ type situations, where an individual has ‘buried his head in the sand’ and failed to make any inquiry which would have revealed the false claim.” *United States v. Entin*, 750 F. Supp. 512, 518 (S.D. Fla. 1990) (quoting *False Claims Reform Act of 1985*, S. Rep. No. 345, 99th Cong., 2nd Sess., reprinted in 1986 U.S. Code Cong. & Admin. News 5266).

A. Halifax Knowingly Presented False or Fraudulent Claims to the United States for Approval

As set forth in section V, the Medicare claims identified by the United States as having been submitted by Halifax in violation of the Stark Law are false because: (1) a financial

relationship existed between Halifax and the Medical Oncologists, (2) the Medical Oncologists referred patients to Halifax for DHS, and (3) the financial relationships do not meet a statutory or regulatory exception because the agreements take into account the volume or value of referrals. It is undisputed that Halifax, in turn, presented to the government thousands of Medicare claims for DHS referred by the Medical Oncologists. *See* Declaration of Ian Dew (Ex. 36). The Stark Law expressly prohibits Medicare from paying these claims. 42 U.S.C. § 1395nn(g)(1).

The undisputed facts make clear that Halifax acted with reckless disregard or deliberate ignorance of the law from the very inception of the employment agreements at issue. In conjunction with the publication of regulations implementing the Stark Law, CMS published comments clearly stating that payments based on a percentage of either revenue, collections, or expenses all varied with the volume or value of referrals because they “do not meet the requirement that compensation be fixed in advance.” 66 Fed. Reg. 856 (Jan. 4, 2001), at 877. Given this published position, Halifax could not have reasonably concluded that the medical oncology employment agreements, which varied based on the revenue and expenses of the hospital’s medical oncology program, did not vary with the volume and value of referrals. *See Heckler v. Cmty. Health Servs. of Crawford*, 467 U.S. 51, 64 (1984) (“[a]s a participant in the Medicare program, respondent had a duty to familiarize itself with the legal requirements”); *Anesthesiologists Affiliated v. Sullivan*, 941 F.2d 678, 681 (8th Cir. 1991) (if the defendants believed at the time that there was an ambiguity, they had a duty to inquire and clarify any such ambiguities). This is the exact “‘ostrich’ type situation” the FCA knowledge standard was meant to address.

Halifax’s reckless disregard of the law is evident when juxtaposed with the ease with which relator, who is not an attorney, was able to identify the problematic nature of the medical

oncology employment agreements. Solely based on watching a one hour training video at Halifax and attending a health care compliance seminar, Ms. Kunz determined that the Medical Oncology employment agreements may violate the Stark Law. SUMF ¶ 48. Once relator shared this information with her supervisors, Halifax decided it was necessary to amend the employment agreements, entering into new contracts effective March 1, 2009. SUMF ¶ 51. Given these circumstances, it strains credulity to envision a scenario whereby Halifax, simply by exercising a minimal level of regard for the law, would not have come to the same conclusion as a layperson regarding the improper nature of the Medical Oncologists' employment agreements.

The record is replete with evidence demonstrating that Halifax acted with knowledge that it was violating the Stark Law. In periodic advisories and transmittals, the chief compliance officer, Mr. George Rousis, updated Halifax executives, including the chief financial officer and the general counsel, on recent developments of interest regarding the Stark Law. SUMF ¶ 45. Specifically, on March 26, 2004, Mr. Rousis summarized recent CMS Stark regulations and advised Halifax leadership that "CMS eliminated a proposed restriction on productivity bonuses, making it clear that physician employees may be paid bonuses based on their personal productivity (but not referrals for ancillary services)." *Id.* Even after its own chief compliance officer disseminated information that physician bonuses could not be based on "referrals for ancillary services," Halifax, with full knowledge that Medicare could not reimburse Halifax for any services performed in violation of the Stark Law, entered into employment agreements whereby the Medical Oncologists received bonuses derived from revenue generated from ancillary services such as outpatient hospital services and outpatient drug utilization. *Id.*

In response to concerns raised by Ms. Kunz with respect to the legality of the Medical Oncologists' employment agreements, Halifax's then-associate general counsel in a memo dated

November 2008 determined that the agreements providing compensation based on operating margin “is not permitted under the STARK regulations.” SUMF ¶ 50. Ms. Pike was unequivocal that the Medical Oncologists “may only be incentivized based on their personally performed services. The current incentive structure takes into account much more than personally performed services.” *Id.* Ms. Pike shared her conclusion with, among others, Halifax’s general counsel and the relator.⁷ The general counsel, in turn, advised Thomas Garthwaite, the service line administrator for Halifax’s medical oncology program, that the contracts violated the Stark Law. *Id.*

Deposition testimony further demonstrates Halifax knew that the operating margin bonus provision in the medical oncology employment agreements varied with the volume or value of referrals. During his deposition, Halifax’s compliance officer, while attempting to label the issue as “undecided,” admitted that the Medical Oncologist compensation varied with referrals.

Q. You think a provision that’s based on the operating margin of the medical oncology program is an open question about whether it varies with volume or value of referrals?

A. Yes, I think that’s an open question.

⁷ Halifax for the first time on May 15, 2013, approximately one month after the close of discovery and pursuant to Judge Smith’s Order (Dkt. No. 266), notified the United States that it intended to rely on advice of counsel. As set forth in both the United States’ Cross-Motion for Exclusion of Evidence (Dkt. No. 231) and Motion to Amend the Second Amended Case Management and Scheduling Order (Dkt. No. 271), the United States throughout discovery asked Halifax whether it was either asserting a defense of advice of counsel or relying on advice of counsel to negate the FCA’s knowledge element. Halifax repeatedly stated it was not relying on advice of counsel in any way. Consistent with this position, Halifax withheld from production attorney-client communications, refused to answer interrogatories, and instructed witnesses not to answer certain questions at depositions based on attorney-client privilege. Because Halifax did not assert advice of counsel until after the close of discovery, and it is unclear whether Halifax has produced all responsive documents in support of this defense, and the United States has not had the opportunity to seek any discovery on this defense, and because Judge Smith declined to extend the deadline for filing dispositive motions set forth in the Second Amended Case Management and Scheduling Order (Dkt. No. 189), the United States submits that it would be inappropriate for Halifax to rely on any evidence asserting that it relied on the advice of counsel, and that any such information should be stricken from the record.

MR. STEPHENS: Objection as to form, asking for a legal conclusion.

BY MR. SCHWARTZ: Q. Okay. Why do you think that's an open question?

A. Because there can be an inverse relationship between margin and referrals.

Q. How so?

A. Because the purpose of the incentive was for the oncologists to assist the hospital in running an efficient department. It would be possible to increase the margin with -- and still -- and refer less to the hospital or the same -- keep the referrals the same and increase margin.

Q. So you could refer more patients to the hospital and the margin would go down potentially?

A. No, that's not what I said. I said you can refer less patients, have the margin go up and thereby increase the incentive.

Q. Okay. So you could refer less patients and the margin could go up, correct?

A. Correct.

Q. So wouldn't that vary with the volume or value of referrals?

A. Yes, but in a good way.

SUMF ¶ 43.

Based on these uncontroverted facts, Halifax knew within the meaning of the FCA that it was submitting claims for payment by Medicare in violation of the Stark Law. As a result, Halifax violated the FCA and the United States should be granted summary judgment.

B. Halifax Made False Records or Statements to Induce the United States to Pay False Claims

FCA liability also is appropriate as to those who knowingly make, use, or cause to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the government. See 31 U.S.C. § 3729(a)(2). *Hopper v. Solvay Pharmaceuticals, Inc.*, 588 F.3d 1318, 1327 (11th Cir. 2009).⁸

⁸ If the current version of the statute (31 U.S.C. § 3729(a)(1)(B)) applies, there is an additional requirement that the government show that the defendant intended to affect the government's payment decision, which is demonstrated by a showing that "people usually intend the natural consequences of their actions." *Reno v. Bossier Parish School Bd.*, 520 U.S. 471, 487 (1997); see also *Personnel Adm'r of Massachusetts v. Feeney*, 442 U.S. 256, 277 (1979) (recognizing "the presumption, common to the criminal and civil law, that a person intends the natural and foreseeable consequences of his voluntary actions."); *United States v. Lawrence*, 405 F.3d 888, 899 (10th Cir. 2005) (approving jury instructions in Medicare fraud case permitting jury to infer that "a person intends the natural and probable consequences of acts knowingly done or knowingly omitted."). Here, there is no dispute that the natural consequence of the defendants' violation of the Stark Law is the submission of false claims to the government.

The record evidence clearly establishes that Halifax’s provider agreements and Medicare claims contained false statements because they falsely certified that Halifax was in compliance with federal program legal requirements, including the Stark Law. On multiple occasions Halifax signed the Medicare provider agreement, expressly stating that it agreed to abide by all Medicare rules, regulations, and instructions, and that payment was conditioned on compliance with all requirements, “including, but not limited to, the Federal anti-kickback statute and the Stark law.” SUMF ¶¶ 8, 10. Halifax also certified the veracity of the information contained on every claim form it filed for Medicare reimbursement, acknowledging “[a]ny one who misrepresents or falsifies essential information to receive payment from Federal funds requested by this form may upon conviction be subject to fine and imprisonment under applicable Federal Laws.” SUMF ¶¶ 6, 8, 16.

By virtue of Halifax’s submission of Medicare claims for reimbursement, there can be no question that Halifax’s false statement of compliance with all Medicare statutes were made in order to get the United States to pay false claims—Medicare claims for reimbursement submitted in violation of the Stark Law. Thus, the United States should be granted summary judgment on its claim that Halifax violated 31 U.S.C. § 3729(a)(2).

C. Halifax Knowingly Made False Statements to the United States to Avoid the Obligation to Return Medicare Overpayments

Halifax’s FCA liability also can be predicated on the use of false statements to conceal or avoid an obligation to pay money to the United States. 31 U.S.C. § 3729(a)(1)(G).

Halifax’s obligation to make restitution to the government once it learned of the Stark Law violations at issue arose under: (1) the Stark Law itself, 42 U.S.C. § 1395nn(g)(2), which requires Medicare providers to “refund on a timely basis” any amounts billed in violation of the statute; and (2) the regulations implementing the Stark Law, 42 C.F.R. § 411.353, which require

that any entity collecting payment for a health care service “performed under a prohibited referral must refund all collected amounts on a timely basis.”

For the reasons discussed with regard to other provisions of the FCA in sections VI.A and VI.B, the false statements made by Halifax that it was in compliance with all Medicare rules and regulations on its provider agreements and on each claim submitted for reimbursement violated 31 U.S.C. § 3729(a)(1)(G). Halifax knowingly did so with the understanding that if it advised Medicare of the structure of the compensation arrangement with the Medical Oncologists, which violated the Stark Law, Medicare could not have reimbursed Halifax for any claims submitted for DHS and would have required Halifax to pay back the money previously received.

D. False Claims Act Damages are Indisputable

Under each of the above-mentioned provisions of the FCA, any person who violates the FCA is liable to the United States for civil penalties “plus 3 times the amount of damages which the government sustains because of the act of that person.” 31 U.S.C. § 3729(a)(1). As set forth in section V, there is no factual basis for concluding that the government’s damages are less than \$34,268,667. Based on Halifax’s knowing submission of claims to Medicare in violation of the Stark Law, the FCA entitles the United States to treble damages, or \$103,806,001, plus statutorily mandated civil penalties of between \$5,500 and \$11,000 for each of the 45,442 false claims submitted by Halifax to the United States for payment.

VII. THE UNITED STATES IS ENTITLED TO SUMMARY JUDGMENT ON HALIFAX’S AFFIRMATIVE DEFENSES NOS. 1-3, 5-7, AND 9

The United States should also be granted summary judgment on seven of Halifax’s nine affirmative defenses. Halifax raised affirmative defenses of failure to state a claim (affirmative defense 1), estoppel (affirmative defense 2), waiver (affirmative defense 3), limitations on damages (affirmative defense 5), fraud with particularity (affirmative defense 6), public

disclosure (affirmative defense 7), and reservation of defenses (affirmative defense 9). In denying the United States' motion to strike these affirmative defenses, the Court said, "To the extent that discovery reveals that these defenses lack support, they should be withdrawn by the Defendants or attacked via a motion for summary judgment." Order (Dkt. No. 119), at 2. Discovery has now revealed Halifax's affirmative defenses are baseless. Because Halifax has not withdrawn the defenses, this Motion for Partial Summary Judgment should be granted.

A. Halifax's "Affirmative Defenses" are not Affirmative Defenses

1. Failure to State a Claim; Fraud with Particularity

A defendant's evidence that the plaintiff has failed to meet its burden of proof is not an affirmative defense. *In re Rawson Food Service, Inc.*, 846 F.2d 1343, 1349 (11th Cir. 1988) ("A defense which points out a defect in the plaintiff's prima facie case is not an affirmative defense."); *Zikovic v. Southern California Edison Co.*, 302 F.3d 1080, 1088 (9th Cir. 2002).

Halifax's first and sixth affirmative defenses are not proper affirmative defenses because they attack only the United States' *prima facie* case and do not seek to avoid liability. *See Ford Motor Co. v. Transport Indemnity Co.*, 795 F.2d 538, 546 (6th Cir. 1986); *Pandora Jewelers 1995, Inc. v. Pandora Jewellery, LLC*, 2010 WL 5393265 at *2 (M.D. Fla. Dec. 21, 2010); *Quintana v. Baca*, 233 F.R.D. 562 (C.D. Cal. 2005) (striking defense of "failure to state a claim" because "it is not an affirmative defense that must be pled or waived"); *see also* 5 Wright & Miller, *Federal Practice and Procedure* 3d, § 1381. The Court already rejected these "defenses" when it denied Halifax's motion to dismiss the Complaint in Intervention. *See generally* Order Denying in Part and Granting in Part Halifax's Motion to Dismiss (Dkt. No. 109).

Even assuming that the failure to state a claim and plead fraud with particularity are in fact affirmative defenses, Halifax claims that the United States' failure to "specif[y] what

constitutes a ‘referring physician’ or a ‘referral’ under the Stark Law.” Halifax’s Amended Objections and Responses to the United States’ Interrogatory No. 2 (Ex. 33). Halifax is not relying on any other information in support of these defenses. *See* Rousis 30(b)(6) Depo. Tr. (Feb. 20, 2013), at 156:13-20, 158:10-16, 162:20-23 (Ex. 34). As explained above, the United States has specified who is a referring physician and the claims that constitute referrals under the Stark Law. *See, supra* section IV.B.

2. Reservation of Defenses

Reservation of defenses that have not been raised is not a proper affirmative defense at this stage of the litigation. If Halifax had additional affirmative defenses that it intended to raise, it should have already sought leave of Court and amended its answer.

B. Halifax Asserts Affirmative Defenses that are Inapplicable to the United States

1. Public Disclosure

Public disclosure is not an affirmative defense to a claim by the United States. The FCA’s public disclosure bar is a jurisdictional limit to FCA cases brought by a relator, but does not bar FCA claims brought by the United States or by a relator in which the United States intervenes. *See Rockwell Int’l Corp. v. United States*, 549 U.S. 457, 478 (2007). Indeed, the public disclosure bar expressly exempts an action “brought by the Attorney General.” 31 U.S.C. § 3730(e). Because the public disclosure bar is inapplicable to claims brought by the United States, Halifax’s affirmative defense as to the United States’ claims fails.

2. Waiver and Estoppel

Waiver and estoppel are not affirmative defenses that are available against the United States in a FCA case. “[E]quitable estoppel will not lie against the Government as it lies against private litigants.” *Office of Personnel Mgmt. v. Richmond*, 496 U.S. 414, 419, (1990); *see also*

Johnson v. Guhl, 357 F.3d 403, 409 (3d Cir. 2004). In particular, “claims for estoppel cannot be entertained where public money is at stake.” *Richmond*, 496 U.S. at 429; *see also Community Health Servs. of Crawford*, 467 U.S. at 66 (rejecting a health care provider’s attempt to avoid administrative recoupment of overpayments made under the Medicare program by asserting equitable estoppel against the Government). The Eleventh Circuit has followed *Richmond* squarely, rejecting estoppel arguments against the Government. *See Shuford v. Fidelity Nat. Property & Cas. Ins. Co.*, 508 F.3d 1337, 1343 (11th Cir. 2007) (applying *Richmond* and rejecting estoppel defenses against an insurance company acting as a fiscal agent of the United States, where the insurance company provided benefits paid from the federal treasury). Because public money is at stake in this case, in the form of Medicare payments, Halifax’s affirmative defenses based on estoppel fail as a matter of law.

Waiver is also an equitable defense, and it is therefore precluded under *Richmond*. 496 U.S. at 419; *see also Haynes v. Level 3 Commc’ns, LLC*, 456 F.3d 1215, 1226 n.13 (10th Cir. 2006) (describing waiver as an “equitable doctrine[]”). Further, “the only governmental body authorized to waive or ratify the rights of the United States [in an FCA case] is the Department of Justice.”⁹ *United States ex rel. Dye v. ATK Launch Sys., Inc.*, No. 1:06-CV-39 TS, 2008 WL 4642164, at *3 (D. Utah Oct. 16, 2008); *see also U.S. ex rel. Monahan v. Robert Wood Johnson Univ. Hosp.*, 2009 WL 4576097 (D.N.J. Dec. 1, 2009), at *7 (“Violations of the FCA . . . may only be waived by the Department of Justice, and the unauthorized statements of United States agents may not serve to waive the Government’s claims.”). Accordingly, a waiver defense to an FCA claim fails if Defendant “has not pled that the DOJ waived these rights.” *United States v.*

⁹ The Department of Justice (DOJ) has the sole responsibility to conduct litigation under the FCA. 28 U.S.C. § 516 (conduct of litigation in which the United States is a party is reserved to DOJ except as otherwise authorized by law); 31 U.S.C. § 3730 (a) (the Attorney General investigates and brings actions under the FCA); 28 C.F.R. § 0.45 (d) (FCA claims are “assigned to, and shall be conducted, handled, or supervised by, the Assistant Attorney General, Civil Division”).

Cushman & Wakefield, Inc., 275 F. Supp. 2d. 763, 771 (N.D. Tex. 2002); *see also Hernandez, Kroone and Assocs., Inc. v. United States*, 95 Fed. Cl. 395, 398 (2010) (striking waiver defense because defendant did not allege that DOJ waived Government's FCA claims). Because equitable defenses do not apply against the United States, and because there is no allegation or evidence that the United States waived the claims at issue in this action, Halifax's affirmative defenses based on waiver fail as a matter of law.

VIII. CONCLUSION

For the foregoing reasons, the United States respectfully asks the Court to grant this Motion for Partial Summary Judgment and:

- 1) Award the United States \$102,806,001 in damages;
- 2) Award penalties in an amount of \$5,500 to \$11,000 for each of the 45,442 claims; and
- 3) Dismiss Halifax's Affirmative Defenses Nos. 1-3, 5-7, and 9.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on May 28, 2013, I caused a true and correct copy of the foregoing to be filed with the Court's CM/ECF system, which will send an electronic notice of the filing to all counsel of record.

/s Adam J. Schwartz
ADAM J. SCHWARTZ
Trial Attorney